

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2087760	(X3) Date Survey Completed 06/27/2018
Name of Provider or Supplier Kinder Pediatrics, Pc	Street Address, City, State 1201 River Avenue, Lakewood, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</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 maintain the attestation statement for the Microbiology events 3-2017 & 1-2018 with the American Proficiency Institute. The TP # 1 listed on the CMS form 209 confirmed 6/27/18 at 11:00 am that all PT records were not maintained.</p>
D5477	<p>CONTROL PROCEDURES 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</p>

manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check QC on each batch of Selective Strep Agar (SSA) used for Throat Culture testing from 1/3/17 to the date of the survey. The findings include: 1. The laboratory did not check SSA for: a. Ability to support growth. b. Ability to select or inhibit specific organisms c. Sterility 2. The TP # 1 listed on the CMS form 209 on 6/27/18 at 10:30 am that the laboratory did not perform the above-mentioned QC checks.

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 the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for two out of four TP from 1/3/17 to the date of the survey. The TP # 1 listed on the CMS form 209 confirmed on 6/27/18 at 10:30 am that all TP did not have education records.