

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0955135	(X3) Date Survey Completed 03/22/2018
Name of Provider or Supplier Pediatric And Adolescent Medicine Llp	Street Address, City, State 495 Central Park Avenue, Suite 305, Scarsdale, NY	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on no proficiency test verification records and an interview with the laboratory nurse/testing person, the laboratory failed to verify the accuracy of spun urine test procedure. Findings Include: On March 22, 2018, at approximately 11:45 PM and confirmed by the laboratory nurse/testing person, the laboratory failed to perform twice annual verification for the spun urine microscopy procedure performed from the date of the last survey November 29, 2016, through March 22, 2018. Approximately 8 patient specimens were tested and reported for the spun urine microscopy procedure performed.</p>
D5401	<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 review of records and interview with the laboratory nurse/testing person at around 11:45 am on March 22, 2018, the laboratory failed to have a written procedure for the spun urine test. The laboratory nurse/testing person confirmed that the laboratory failed to have a written procedure for microscopy of spun urine.</p>

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor's review of laboratory procedures and no records for twice a year verification and an interview with the laboratory nurse/testing person, the laboratory director failed to perform twice annual verification and have a procedure for spun urine microscopy.