

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0914012	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Century Airport Pediatrics Pc	Street Address, City, State 2625 Harlem Road, Suite 210, Cheektowaga, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the American Proficiency Institute (API) Proficiency Testing (PT) records and confirmed in an interview with the laboratory testing person, the laboratory failed to evaluate, perform and document the review of the PT Summary reports for all three test events in 2016 and the 1st and 2nd events of 2017.</p>
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 surveyor's review of the API PT records, the lack of twice year verification documentation for urine colony counts and confirmed in an interview with the laboratory testing person, the laboratory failed to verify, at least twice annually, the accuracy of the urine colony counts for the calendar years 2016 and 2017. FINDINGS: The laboratory testing person confirmed on 1/30/2018 at approximately 2:00 PM, that the laboratory failed to perform a twice year verification in calendar years 2016 and 2017 for the urine colony counts. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY OF JANUARY 27, 2016.</p>
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's Quality Assessment (QA) policy, QA 2016 and 2017 records, and confirmed in a interview with the laboratory testing person, the laboratory failed to follow their establish QA policy and identify issues and take corrective action for the bacteriology testing in the calendar year 2016 and 2017. FINDINGS: The testing person confirmed on 01/30/2018 at approximately 2:30 PM, that the laboratory failed to identify issues and take corrective action for the following: a. review and evaluate the API PT summary reports for all three test events for 2016 and 1st & 2nd events of 2017. b. perform and document twice year verification for urine colony counts for the calendar years 2016 and 2017. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY OF JANUARY 27, 2016.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor's review of laboratory records and confirmed in an interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. laboratory implemented and maintained the plan of correction from the survey conducted on 01/27/2016; 2. laboratory's QA program for bacteriology was maintained, refer to D6021. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY OF JANUARY 27, 2016.

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 the Quality Assessment (QA) policy and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure that the general laboratory systems QA reviews identified issues and that corrective

actions were taken. Refer to D5211, D5217 and D5291. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY OF JANUARY 27, 2016.