

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0914012	(X3) Date Survey Completed 09/28/2022
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the ESA Lead Care II Quality Control (QC) records, analyzer manual and an interview with the testing person, the laboratory failed to follow the Magellan Diagnostic Lead Care manufacturer's QC requirement. FINDINGS: 1. The testing person confirmed on September 28, 2022, at approximately 10:30 AM, the laboratory did perform and document the QC results for Lead Care II Controls I & II for the following: a. Kit Lot # 053122 expiration date 2/19/2023- QC Lot # 2214M expiration date 02/17/2023 The control range for level II was 19.3-27.5 the recorded range was 28.0 b. Kit Lot # 053122 expiration date 2/19/2023- QC Lot # 2215M expiration date 02/28/2023 The control range for level I was 3.0-10.8 the recorded range was 11.4 2. Approximately 52 patient specimens were tested and reported from 8/15/2022 through 09/21/2022 when control results were out of range.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of competency assessment policy and an interview with the testing</p>

person, the laboratory failed to follow their written competency evaluation policy for the two of six testing personnel. FINDINGS: 1. The laboratory's competency evaluation policy includes the six required components for competency assessment, including training, six-month for the first year of testing and annually thereafter. 2. The testing person confirmed on 9/28/22 at approximately 10:00 AM that the laboratory director failed to perform the annual competency evaluation for the two of six testing personnel in the calendar year 2021. Refer to D6054.

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 review of the Quality Assessment (QA) policy and an interview with the testing person, the laboratory failed to follow their establish QA policy and identify problems. FINDINGS: 1. The laboratory failed to follow their establish QA policy and identify the failure to perform annual competency evaluations on two of the six testing personnel, and out of range incubator temperature from 7/1/2021 through 12/31/2021. 2. The laboratory testing person, confirmed on 9/28/2022 at approximately 11:30 AM, the laboratory failed to follow their establish QA policy and identify problems on the 2021 QA document. Refer to D5413 and D6021 .

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the laboratory the incubator temperature records for the calendar years 2021 through survey date and interview with the testing person, the laboratory failed to follow the manufacturer's temperature requirement for throat culture and urine colony counts testing. FINDINGS: 1. The laboratory performs throat culture. The manufacturer of the throat culture media used for testing and the laboratory's temperature policy requires that the incubator temperature to be in the range of 35-38 degree Celsius. The laboratory converted to 95- 100.4 Fahrenheit. a. the testing personnel recorded the temperatures 100.7-101.4 F from 1/1/2021 through 12/31/2021. 2. The incubator temperature was out of range for the following: 18 days in July 2021 29 days in August 2021 24 days in September 2021 20 days in October of 2021 2 days in November 2021 30 days in December 2021 3. Approximately 1,000 patients were tested for urine colony counts and throat cultures during the above dates 4. The testing person confirmed on September 28, 2022 at approximately 11:30 AM

	<p>that the the laboratory failed to follow the manufacturer's temperature requirement for throat culture and urine colony count testing. Refer D6021.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Maintained their written QA policy for all phases of laboratory testing, Refer to D6021; 2. Established competency assessment policy was followed, Refer to D6054.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's QA policy, 2021 QA documentation and an interview the testing person, the laboratory director failed to follow the establish QA procedure for having an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory system. Refer to D5209, D5291, D5413 and D6054.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency assessment policy, lack of competency evaluations for two out of six testing personnel and confirmed in an interview with the laboratory testing person, the laboratory director, acting as the technical consultant, failed to assess the two of the six testing personal in 2021 Refer to D5209</p>