

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0717051	(X3) Date Survey Completed 04/13/2022
Name of Provider or Supplier Pediatric Healthcare Associates	Street Address, City, State 4 Corporate Dr Suite 290, Shelton, CT	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when temperatures exceeded established acceptable ranges in the subspecialty of bacteriology for the period of January 2021 through April 13, 2022. Findings include: 1. Record review on 04/13/2022 of the laboratory's 'Incubator Temperature Log' for the period of January 2021 through April 13, 2022 revealed the following: a. Acceptable temperature range was 34 to 38 Degrees Celsius. b. Temperatures were out of range for 116 of 319 working days with corrective action not documented. 2. Staff interview on 4/13/2022 at 11:25 AM with the Nurse Supervisor verified the following: a. Acceptable temperature range was 34 to 38 Degrees Celsius. b. The temperatures were out of range and documentation of corrective action was not recorded. 3. The laboratory performs 124 tests annually in the subspecialty of bacteriology.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to follow its written quality assurance policy to monitor, assess and when necessary correct issues surrounding equipment checks in the subspecialty of bacteriology for the period of January 2021 through April 13, 2022. Findings include: 1. Record review on 04/13/2022 of the laboratory's 'Quality Assurance Policy' revealed "Review of temperature charts & lab counters and equipment disinfection chart for completeness and accuracy of daily data recording, by site manager or supervisor". 2. Record review on 04/13/2022 of the laboratory's 'Incubator Temperature Logs' revealed the following: a. Acceptable temperature range was 34 to 38 Degrees Celsius. b. Temperatures were out of range for 116 of 319 working days. c. Lack of documentation of active review by site manager or supervisor and when necessary, corrective action when temperature was out of range. 3. Staff interview on 4/13/2022 at 11:30 AM with the Nurse Supervisor (NS) confirmed the above findings. The NS further remarked he/she was unaware the need to review temperature logs for accuracy. 4. The laboratory performs 124 tests annually in the subspecialty of bacteriology.