Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0717051	10/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Healthcare Associates	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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: A. Based on surveyor observation, record review and staff interview, laboratory personnel failed to follow the established quality control plan (QCP) in the specialty of microbiology. Findings include: 1. Record review on 10/28/19 of the quality control procedures portion of the laboratory's Uricult procedure manual revealed: a. "Upon arrival, examine 2 Uricult culture-paddles per box for: cracked vials, cracked media, dehydration or discoloration of media, freezing, unequal filling, excessive bubbles, contamination, media separated from paddle, excess moisture. b. "Remove the certificate of analysis (COA) from the package insert for each new lot number and attach to your quality control (QC) records. Record the date product is received, product lot number and PASS/FAIL visual inspection results along with the technician's initials on the QC log." 2. Record review on 10/28/19 of the laboratory's quality QCP portion of the individualized quality control plan (IQCP) revealed: a. "PHA relies on the established QCP provided by Uricult." b. "Due to the risk assessment provided by Uricult, we rely on the manufacturer's quality analysis insert." 3. Record review on 10/28/19 of the laboratory's 'Uricult Quality Control Record Log' revealed: a. Visual Inspection Procedure, "Upon arrival, examine 2 Uricult culture-paddles per box for: cracked vials, cracked media, dehydration or discoloration of media, freezing, unequal filling, excessive bubbles, contamination, media separated from paddle, excess moisture." b. "Record the visual inspection results on the form below." c. The last documented visual inspection was for lot number 1880256 with an expiration date of 9/17/19. d. The last COA attached to the QC log was for lot number

	1880256 with an expiration date of 9/17/19. 4. Surveyor observation on 10/28/19 at 10:30 AM revealed the Uricult media currently in use has lot number 1889419 with an expiration date of 2/11/20. This lot number was not entered on the Uricult quality control log and the COA was not attached. 5. Staff interview with the technical consultant on 10/28/19 at 10:35 AM confirmed the laboratory failed to follow the established IQCP by saving the certificate of analysis and documenting the physical characteristics of each lot and shipment of Uricult media. B. Based on record review and staff interview, the laboratory failed to follow the established Quality Assurance (QA) plan for Uricult testing in the Uricult IQCP plan. Findings include: 1. Record review on 10./28/19 of the laboratory's QA portion of the Uricult IQCP revealed: a. "Quarterly audit by clinical nurse manager of manual log results against EHR documentation." b. "Quarterly audit by clinical nurse manager of the following: Daily Room Temperature log, Uricult Quality Control Log/attached Certificate of Analysis, Daily temperature log." 2. Record review on 10/28/19 of the laboratory's 'Quarterly CLIA Audits' log revealed: a. The laboratory did not check Uricult manual log results against the EHR documentation for 4 of 4 quarters in 2018. b. The laboratory did not check Uricult manual log results against the EHR documentation for 3 of 3 quarters from 1/1/19 through 9/30/19. 3. Record review on 10/28/19 of random patient Uricult records checked against the EHR documentation reveled: a. Patient #1, collected on 7 /30/19 - Uricult result was not written on the manual log. b. Patient #2, collected on 8 /29/19 - Uricult result was not written on the manual log. c. Patient #3, collected on 10 /1/19 - Uricult result was not written on the manual log. d. Patient #4, collected on 2/1 /19 - EHR documentation does not match manual log. e. Patient #5, collected on 10/26 /19 - EHR documentation does not match manual log. f. Patient #6, collected on 10/18 /19 - EHR documentation does not match manual log. g. Patient #7, collected on 8/29 /19 - EHR documentation does not match manual log. 4. Record review on 10/28/19 of the laboratory's 2018 and 2019 temperature charts revealed the charts are not signed as reviewed by the clinical nurse manager. 5. Staff interview with the clinical nurse manager on 10/28/19 at 11:00 AM confirmed the findings in B1 through B4 above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 take corrective action when the laboratory incubator temperature was out of range in the subspecialty of bacteriology. Findings include: 1. Record review on 10/28/19 of the laboratory's 'Incubator Temperature Log' revealed: a. Acceptable incubator temperature range is 34 to 38 degrees Celsius. b. Corrective action when the incubator temperature was out of range was not documented for 43 of 261 working days in 2018. c. Corrective action when the incubator temperature was out of range was not documented for 19 of 218 working days from 1/1/19 through 10/28/19. 2. Record review on 10/28/19 of the laboratory's 'Uricult procedure' revealed, "Upon inoculation of urine, immediately incubate at 34 to 38 degrees C." 3. Record review on 10/28/19 of the Uricult package insert' revealed, "Place inoculated Uricult vial upright in incubator (36C 2C) for 18 to 24 hours." 4. Record review on 10/28/19 of the laboratory's 'Refrigerator Temperature

	Log' revealed: a. Acceptable refrigerator temperature range is 35 to 46 degrees Fahrenheit. b. Corrective action when the refrigerator temperature was out of range was not documented for 8 of 261 working days in 2018. c. Corrective action when the refrigerator temperature was out of range was not documented for 2 of 218 working days from 1/1/19 through 10/28/19. 5. Staff interview on 10/28/19 at 10:00 AM with the technical consultant confirmed the above findings.