Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0686355	11/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Greenwich Pediatric Associates	8 West End Ave, Old Greenwich, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to investigate or take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. College of American Pathologists (CAP) PT record review on 11 /25/19 revealed: a. Unacceptable test results for 2018- Event 2: Sample ID: FH15-08: Absolute granulocytes. b. Investigation or remedial action was not documented for the above unacceptable results. d. The PT events were signed as reviewed by the laboratory director (LD). 2. Staff interview with current LD on 11/25/19 at 11:00 AM confirmed the laboratory did not have documentation for investigation of the unacceptable PT result. The current LD further stated he/she was unaware what investigation and/or corrective action was taken by the previous LD for the unacceptable PT score obtained. 3. The laboratory performs 1,536 hematology tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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. 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. Findings include: 1. Record review on 11/25/19 of the laboratory's "Incubator Quality Control Record" for 2019 revealed: a. Acceptable incubator temperature range is 34 to 38 degree Celsius (C). b. Incubator temperature was out of acceptable limits on 240 of 281 working days in 2019. c. Documentation of corrective action for the above unacceptable temperature was not recorded. 2. Record review on 11/25/19 of the package inserts for Uricult test kit revealed acceptable incubator temperature is 36 +/- 2 degree C. 3. Staff interview with the laboratory director on 11/25/19 at 12:30 PM confirmed the above findings. 4. The laboratory performs 200 Uricult tests annually. 5. This is a repeat deficiency.