Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 07D0686355	**(X3) Date Survey Completed** 02/18/2021
Name of Provider or Supplier Greenwich Pediatric Associates	**Street Address, City, State** 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**
D0000	A proficiency testing desk review of the Greenwich Pediatric Associates Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on an off-site desk review of the 2020 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and College of American Pathologists (CAP) PT records and email communication and telephone interview

	with the practice manager, the laboratory failed to successfully participate in two consecutive testing events in the specialty of Hematology resulting in unsuccessful PT performance. Refer to citation D2123 and D2131.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on an off-site desk review of the laboratory's 2020 hematology proficiency testing (PT) results reported by the College of American Pathologists (CAP) and an email and telephone interview with the practice manager, the laboratory failed to participate in two Hematology testing events resulting in unsatisfactory performance with scores of 0. Findings include: 1. Record review of the CAP FH15 2020 Centrifugal Hematology Survey PT records on 2/18/21 revealed the following: a. Event FH 15-B Original Evaluation with an exception resource code: '40 = Results for this kit were not received' b. Event FH 15-C Shipment packing slip with ship date 11 /23/2020, kit#32871887 and delivered to the laboratory on 11/25/2020 with no Original Evaluation report. 2. Email communication and telephone interview on 2/17 /21 at 11:00 AM with the practice manager confirmed the following: a. The laboratory failed to participate in 2020 Events B and C. b. Notification to CAP and the State Agency within the time frame for PT result submission of the cessation of hematology testing was not done. c. Hematology patient testing was ceased with the last patient tested on 4/21/2020.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on an off-site desk review of the laboratory's 2020 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and an email and telephone interview with the practice manager, the laboratory failed to achieve satisfactory performance in two consecutive hematology testing events resulting in unsuccessful PT performance. Findings include: 1. Record review of the Center for Medicare & Medicaid Services (CMS) CASPER 0155D Report on 2/18/21 revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores for two consecutive PT events for the Hematology Specialty analyte #0760, and individual analytes: # 0765 Cell I.D. or WBC Differential, #0785 Hematocrit HCT

	(non-waived), #0795 Hemoglobin HGB (non-waived), #0805 White Blood Cell WBC and #0815 Platelets as follows: Year/Event # Analyte # Score 2020 Event 2 0760 0% 0765 0% 0785 0% 0795 0% 0805 0% 0815 0% 2020 Event 3 Analyte # Score 0760 0% 0765 0% 0785 0% 0795 0% 0805 0% 0815 0% 2. Email communication and telephone interview on 2/17/21 at 11:00 AM with the practice manager confirmed the following: a. The laboratory failed to participate in 2020 Events B and C. b. Notification to CAP and the State Agency within the time frame for PT result submission of the cessation of hematology testing was not done. c. Hematology patient testing was ceased with the last patient tested on 4/21/2020. 3. This is the first unsuccessful performance for the specialty of Hematology.