Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0101910	02/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ridgefield Pediatric Associates	38-B Grove St, Ridgefield, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure proficiency testing (PT) samples were handled in the same manner and rotated amongst all testing personnel (TP) in the specialty of hematology. Findings include: 1. Record review of the 2020 College of American Pathologists PT records on 2/23/22 revealed 4 of 5 TP had not tested any PT samples for events two (FH3-B) and three (FH3-C) in the specialty of hematology. 2. Staff interview with the laboratory manager on 2/23/22 at 1:00 PM confirmed PT samples were not being examined in the same manner as patient samples for the events listed above and were tested by one TP. 3. The laboratory performs 124 complete blood count tests annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

	laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process in the speciality of hematology. Findings include: 1. Record review of the laboratory's peer group "Interlaboratory Quality Assessment Program (IQAP)" on 2/23/22 revealed the following: a) Quality control (QC) results for platelets (PLT) and basophil (%) were out of 3 standard deviation (SD) for the high level QC with lot# 372010813 from 1/8/20 through 2/17/20. b) QC results for PLT were out of 3 SD for the high level QC with lot# 372011213 from 4/17/20 through 5/20/20. c) QC results for MCV were out of 3 SD for all three (high lot# 372112813, normal lot# 362112812 and low lot# 352112811) levels QC from 9/10/21 through 10/27/21. d) QC results for MCV were out of 3 SD for all three (high lot# 372113013, normal lot# 362113012 and low lot# 352113011) levels QC from 10/28/21 through 1/3/22. e) QC results for WBC, HGB and Lymphocytes(%) were out of 3 SD for the high level QC with lot# 372113213 from 1/5/22 through 2/10/22. f) IQAP records were not available for review for the month of March 2020 and June 2020 through August 2021. Handwritten documentation for the above QC outliers stated "Monthly review of QC OK, a few parameters where QC is greater than 2 CVI. Manufacturer is contacted to tweak. OK to run patient sample. At least two levels of QC within recommended parameters." 2. Staff interview with the laboratory manager (LM) on 2/23/22 at 11:00 AM confirmed the above findings. The LM further stated there were some staffing changes occurred and they are still learning about laboratory QC policies. 3. The laboratory performs 744 tests in the specialty of hematology annually. 4. This is a repeat deficiency.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to check each lot number and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms in the specialty of microbiology. Findings include: 1. Review of the laboratory's quality control records for Strep Select Agar (SSA) on 2/23/22 revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for each lot number and shipments received in 2020 and 2021. 2. Staff interview with the laboratory manager (LM) on 2

	/23/22 at 1:15 PM confirmed the laboratory did not check each new lot number or shipment of SSA media for their ability to support growth and, as appropriate, select or inhibit specific organisms. The LM stated the laboratory gets 18 shipments of SSA media annually. 3. The laboratory performs 2,571 throat cultures annually in the specialty of microbiology. 4. This is a repeat deficiency.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to investigate or take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review on 2/23/22 of the College of American Pathologists (CAP) PT records for "DJ A-2021 Throat Culture" revealed: a. Unacceptable test scores was obtained for specimen # TC-02. b. Investigation or remedial action was not documented for the above unacceptable PT result. c. The above PT event was signed as reviewed by the LD. 2. Staff interview with the laboratory manager (LM) at 11:00 AM confirmed the laboratory did not investigate the unacceptable PT result. The LM further stated he/she was unaware an investigation was required for PT scores less than 100%. 3. The laboratory performs 2,571 throat cultures per year.