Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2122735	10/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Acorn To Oak Pediatrics	1025 Hwy 80 E, Haughton, LA	

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 Recertification survey was performed on October 11, 2021 at Acorn to Oaks Pediatrics, CLIA ID # 19D2122735. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policy and procedure manual, and the American Proficiency Institute (API) proficiency testing records as well as interview with personnel, the laboratory failed to document remedial actions for unacceptable Hematology scores. Findings: 1. Review of the laboratory's Proficiency Testing policy revealed "The laboratory will seek consultation to remedy the causes of any unsuccessful results and follow approved corrective action". Further review of the Proficiency Testing policy under "Review of Survey Results" revealed "Any result that deem unacceptable requires a complete documentation procedure utilizing the appropriate form. Any corrective action taken will be documented and signed by the director, technical consultant, and testing personnel". 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory received the following unacceptable results: a) 2021 Hematology /Coagulation 1st event: Score for Basophils - 80% b) 2021 Hematology/Coagulation

	1st event: Score for Eosinophils - 80% c) 2021 Hematology/Coagulation 1st event: Score for Lymphocytes - 80% d) 2021 Hematology/Coagulation 1st event: Score for Neutrophils - 80% 3. Further review of the laboratory's API proficiency testing records revealed no documentation of corrective action, investigation, or remedial action for these unacceptable scores. 4. In interview on October 11, 2021 at 2:56 pm, Personnel 2 stated the laboratory did not perform any corrective actions for the unacceptable results since they passed with an 80% score for all. Personnel 2 confirmed the laboratory did not investigate the above identified results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include written, detailed instructions for the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria b) Complete Blood Count: to include what tests are performed and resulted for patient testing and the actions to take when flags occur on patient results c) SARS-CoV-19 testing: to include all platforms and/or test kits utilized for patient testing 2. In interview on October 11, 2021 at 4:28 pm, Personnel 2 confirmed the laboratory did not include the identified policies.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour, review of installation records, policy and procedure manual, and interview with personnel, the laboratory failed to have complete performance verification studies for the Beckman Coulter DxH Hematology analyzer. Findings: 1. Direct observation by the surveyor during the laboratory tour on October 11, 2021 at 1:32 pm revealed the laboratory utilizes the Beckman Coulter DxH Hematology analyzer for Complete Blood Count (CBC) testing. 2. In interview on October 11, 2021 at 1:10 pm, Personnel 2 stated the laboratory received a new Beckman Coulter DxH Hematology analyzer to replace their old one in March 2021. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for performance specification studies. 4. Review of the laboratory's installation records for the Beckman Coulter DxH analyzer revealed the following studies did not have the documentation to support complete precision to include day to day, run to run, within run, and operator variance. 5. In interview on October 11, 2021 at 3:23 pm, Personnel 2 stated the laboratory performed the installation studies along with the service representative for Beckman Coulter but could not find the documentation for precision studies.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D2128.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5403.