Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0705987	04/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pines Road Family Medicine	9111 Susan Drive, Shreveport, 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 Validation Survey was conducted on April 9, 2024 at Pines Road Family Medicine - CLIA # 19D0705987. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and interview with personnel, the laboratory failed to complete procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Personnel Process" policy revealed the policy did not include how the laboratory will demonstrate the following six (6) procedures minimally required for the assessment of competency for testing personnel: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on April 9, 2024 at 9: 50 am, the Technical Consultant confirmed the laboratory's policy did not detail how competency is to be evaluated for testing personnel.
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 observation by surveyor, review of the laboratory's policy and procedures and performance verification records as well as interview with personnel, the laboratory failed to verify complete performance specifications for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 520 hematology analyzer. Findings: 1. Observation by surveyor on April 9, 2024 at 11:00 am during the laboratory tour revealed the laboratory utilizes the Beckman Coulter DxH 520 hematology analyzer for Complete Blood Count (CBC) patient testing. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for performance verification to include accuracy, complete precision, reportable range, and reference range along with the acceptability criteria for each. 3. Review of the laboratory's performance verification records from April 2023 revealed the laboratory did not verify precision to include day-to-day and operator variance along with raw data to support studies. 4. In interview on April 9, 2024 at 11:00 am, the Technical Consultant confirmed the laboratory did not have policy, day-to-day, and operator variance for studies on the Beckman Coulter DxH520 analyzer. 5. Review of the Task 1&3 form provided to surveyor revealed the laboratory performs 2856 Complete Blood Count (CBC) tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of maintenance logs and interview with personnel, the laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for six (6) of twelve (12) months reviewed in 2023 and 2024. Findings: 1. Observation by surveyor during the laboratory tour on April 9, 2024 at 11:30 am revealed the laboratory utilizes the Beckman Coulter DxH 520 hematology analyzer for Complete Blood Count (CBC) patient testing. 2. Review of the maintenance logs for the Beckman Coulter DxH 520 hematology analyzer revealed the laboratory performs the following monthly maintenance: a) Bleach Cycles b) Cleaning the WBC Bath Filter 3. Further review of the April 2023 through March 2024 maintenance logs for the Beckman Coulter DxH 520 hematology analyzer revealed the monthly maintenance was not performed for the following six (6) of twelve (12) months reviewed: a) May 2023 - Bleach Cycles b) June 2023 - Bleach Cycles; Cleaning the WBC Bath Filter c) July 2023 - Cleaning the WBC Bath Filter d) August 2023 - Bleach Cycles; Cleaning the WBC Bath Filter e) October 2023 - Bleach Cycles; Cleaning the WBC Bath Filter f) March 2024 - Bleach Cycles;

	Cleaning the WBC Bath Filter 4. In interview on April 9, 2024 at 11:30 am, the Technical Consultant confirmed the identified monthly maintenance was not performed as required by the manufacturer.
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, review of laboratory policy, performance studies, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Findings: 1. The laboratory failed to verify the performance specifications for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 520 hematology analyzer. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and maintenance records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for six (6) of twelve (12) months reviewed in 2023 and 2024. Refer to D5429.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to complete procedures to assess competency for testing personnel. Refer to D5209.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for six (6) of twelve (12) months reviewed in 2023 and 2024. Refer to D5429.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy and performance studies as well as interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Findings: 1. The laboratory failed to verify the performance specifications for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 520 hematology analyzer. Refer to D5421.