Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1019429	(X3) Date Survey Completed 10/01/2019
Name of Provider or Supplier C R Doc	**Street Address, City, State** 2700 West Kingshighway Suite 4, Paragould, AR	

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
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: Through a review of the new instrument validation for the AcT Diff 2 put into service in March 2019, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to verify the manufacturer's normal ranges were appropriate for the laboratory's patient population. Survey findings include: A. A review of the validation documentation for the AcT Diff 2 Hematology Analyzer, which was put into service in March 2019, revealed that there was no documentation of verification of the manufacturer's normal values for patient testing. B. In an interview at 2:45 pm on 10/1/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory had no documentation of verifying the normal patient ranges in use for the AcT Diff 2.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Through a review of the Coulter AcT diff 2 Operator's Manual, a review of quality control and patient results from the Coulter AcT diff 2, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document function checks as defined by the manufacturer. Survey findings include: A. A review of the Coulter AcT diff 2 Operator's Manual revealed that Instrument Startup is required daily. The Instrument Startup includes a background count for WBC, RBC, Hemoglobin, and Platelet which is recorded as Pass or Fail. The manual lists required corrective actions to take if any or all parameters fail the background count. B. During a review of quality control and maintenance for April 2019 it was determined on 4/22 /2019 the laboratory had documentation of quality control but no documentation of the background counts for the Coulter AcT diff 2 hematology analyzer. The laboratory failed to document background counts on one of twenty-six days in April 2019. C. In a review of patient test reports it was determined that four patients had complete blood counts reported from the Coulter AcT diff 2 analyzer on 4/22/2019. Patients #13600,#11922, #9246, and #18672 were reported on 4/22/2019. D. In an interview at 1:25 on 10/1/2019 laboratory employee #3 (as listed on the form CMS-209) confirmed the laboratory had no documentation of background counts on 4/22 /2019.