Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1013224	02/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Randy D Walker Md Pllc	1553 West Collin Raye Drive, De Queen, 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 validation studies for the Alere Triage Cardiac analyzer performed on November 27, 2019, lack of documentation, and interview with staff, it was determined the laboratory failed to validate the method correlations for Alere Triage Cardiac analyzer to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. Survey finding follow: A. The laboratory utilizes the Alere Triage Cardiac analyzer to process the following analytes: D-Dimer and Cardiac panel. B. A review of the validation studies for the Alere Cardiac analyzer revealed no data was present (at time of survey) to verify the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. C. Upon request, the laboratory was unable to provide method correlation studies performed for the validation of the Alere Triage cardiac analyzer. D. In an interview on 02/04/2021 at 11:30, the technical consultant confirmed that method correlation studies were not performed as part of the validation of the Alere Triage analyzer.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Through observations, a review of Quality Control Plan (QCP) component of Individualized Quality Control Plan (IQCP), Consultant Monthly Report, quality control documentation, observations, lack of documentation and interviews with staff, it was determined the laboratory failed to follow the QCP, and failed to remediate patient test results on days when only one level of Quality Control (QC) was analyzed. Survey finding follow: A. The laboratory has two Alere Triage analyzers on which they perform the following test: Cardiac Panel and D-Dimer. B. A review of the QCP component of the IQCP revealed "Triage Total 5 Control Level 1 and Control Level 2 will be ran every 30 days and each new lot/shipment of Alere Triage test cartridges." C. A review of quality control documentation for August-November 2020 (four of twelve months) revealed the laboratory was performing Triage Level 1 control on analyzer 1 and Triage Level 2 on analyzer 2. The laboratory failed to run 2 levels of controls per analyzer. D. A review of the Consultant's Monthly report dated 11/14/20 revealed the laboratory processed on analyzer 1: 59 D-Dimers, and 118 Cardiac test: on analyzer 2: 14 D-Dimer and 24 Cardiac. E. The surveyor request documentation on patient test remediation during the months were only one level of quality controls were analyzed per instrument. None was provided. F. In an interview on 02/04/21 at 13:00, the technical consultant confirmed the laboratory did not remediate patients test results when only one control level was analyzer per instrument.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the

	technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Through a review of personnel, education records and interview with staff, it was determined the laboratory failed to have a technical consultant who was qualified to provide technical consultation for the testing performed. Survey findings follow: A. A review of personnel and competency records for nine of twelve laboratory staff revealed testing personnel #2 (as listed on form 209) was performing the duties of the technical consultant by assessing competencies. B. A review of education records for twelve of thirteen laboratory personnel revealed testing personnel #2 did not meet the education requirements for Technical Consultant. C. In an interview on 02/04/2021 at 10:00 laboratory personnel #13 (as listed on CMS 209) confirmed testing personnel #2 were assuming the duties of the technical consultant by assessing personnel competencies without having the required education credentials. .