Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2093828	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Five Star Er	8721 Manchaca Rd, Austin, TX	

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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1423 Condition: laboratories performing moderate complexity testing; testing personnel
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 review of the laboratory's quality control records from 2018 in 2019, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control results over time for the Abbott i-STAT (used to test pH, PCO2, PO2 and lactic acid) and the Alere Triage meter (used for testing CK-MB, troponin, myoglobin and d-dimer). The findings included: 1. A review of the laboratory's quality control records from 18 and 19 found: a. The laboratory tested two levels of quality control material once each month and with each cartridge change for pH, PO2, and PCO2 and lactic acid. b. The laboratory tested two levels of quality control material once each month and with each new lot and shipment for D-dimer and Cardiac Markers using the Alere Triage meter. c. The laboratory did not use a Levy Jennings graph or have some other means of monitoring the performance of the

	control material over time. d. The laboratory was asked to provide documentation of having mechanism is place to monitor quality control values over time. No documentation was provided. 2. Interview of the technical consultant listed on the CMS report 209 laboratory personnel report conducted on July 11, 2018 at 10:59 AM confirmed that the laboratory only assessed quality control results daily and did not monitor them over time as required.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the quality control program had been established and maintained for chemistry and hematology. (See D5441)
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel files and staff interview, it was revealed the technical consultant failed to assess the competency for 2 to 15 testing personnel at least semiannually during the first year of testing patient specimens. Findings included: 1. Review of personnel records found onecompetency assessment performed in the first year of testing for testing persons eight and nine listed on the CMS report 209 Laboratory Personnel Report. Testing person eight was hired April 17, 2017. Initial training was completed on June 11, 2017 with the first semiannual competency assessment conducted July 15, 2017. The next competency assessment was completed June 17, 2018. Testing person nine was hired January 22, 2018. Initial training was completed February 10, 2018 with in the first semiannual competency assessment completed June 22, 2018. The next competency assessment noted as an annual competency assessment was completed June 24, 2019 2. Interview of the technical consultant conducted on July 11, 2019 confirmed that the laboratory failed to perform and document semiannual competency assessments during the first year of testing for testing persons eight and nine.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report, personnel records and staff interview, found one of 15 testing personnel did not have the appropriate education credentialsrequired to perform moderate complexity testing (see D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Review of personnel records and interview of facility personnel found the laboratory failed to have documentation of education necessary to qualify one of 15 testing personnel performing moderate complexity testing. The findings included: 1. Review of personnel records for testing person 15 found education completed in Puerto Rico consisting of a Bachelor of Science degree in computerized tomography and associate of science degree in Radiology Technology, neither degrees meeting the minimum education requirements for moderate complexity testing. 2. Interview of facility personnel conducted on April 11, 2019 at 9:53 AM confirmed that the laboratory did not have any other documentation of education available for review.