Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2139333	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quality Care Er, Llc	2675 41st Se Mob#4 Ste 101, Paris, 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
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: . Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) documentation for 2019 and staff interview, the laboratory failed to return PT results to the testing program within the time frame specified. Findings: 1. Review of AAB PT results for 2019 revealed that for the first quarter (Q1) the laboratory showed "No Data Received." 2. In an interview at the site on 10-24-2019, testing person 24 (CMS form 209) stated that the PT results had not been submitted before the deadline, resulting in no score for the blood gas analytes pH, pO2 and pCO2. 3. In a telephone interview at 0950 CDT on 11-13-2019, the laboratory technical consultant (CMS form 209) confirmed the late submission. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on review of AAB PT documentation for 2018 and 2019 and laboratory quality control logs, confirmed by staff interview, the laboratory failed to verify the accuracy of cardiac enzyme and D-dimer testing performed on the Alere Triage analyzer. Findings; 1. AAB PT documentation and laboratory control logs were

	reviewed. Control logs indicated use of theTriage analyzer for cardiac enzyme and D-dimer testing. AAB documentation showed no record of proficiency testing for any of the analytes assayed on the system being reported. Staff members present at the time were unable to produce evidence that required accuracy verification was being performed on the Triage analyzer. 2. In a telephone interview at 0948 CDT on 11-13-2019 the laboratory technical consultant confirmed that no accuracy verification for cardiac enzyme or D-dimer testing was being performed at the site. .
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 surveyor observation, review of available documentation and staff interview, the laboratory failed to verify performance specifications comparable to those established by the manufacturer for the Abbott i-Stat chemistry analyzer with CG4+ testing cartridge before reporting patient test results. Findings: 1. In the course of the survey, verification study documentation for blood gas testing using the Abbott i-Stat chemistry analyzer, was requested. Staff members present at the time were unable to provide such documentation. 2. In a telephone interview at 1550 CDT on 11-07-2019, the laboratory technical consultant confirmed that no verification of manufacturer's specifications regarding accuracy, precision, reportable range or appropriateness of reference ranges had been performed before putting the instrument in use. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . I. Based on review of laboratory procedures, quality control documentation and staff interfiew, the laboratory failed to perform required external quality controls for cardiac enzyme and D-dimer assays using the Alere Triage analyzer at the required frequency. Findings: 1. Laboratory quality control logs were reviewed. Logs for the Alere Triage analyzer using the Triage cardiac panel and D-dimer test cartridges indicated external quality controls performed monnthly and at lot change. In an interview at the site on 10-24-2019 testing person 24 confirmed that this was consistent with laboratory practice. On inquiry he further stated that to his knowledge the laboratory had not developed an individual quality control plan (IQCP) for cardiac

	enzyme and d-dimer assays using the Alere Triage analyzer. 2. Laboratory policy states: "external controls should be tested with each new lot of test materials, or every 30 days." (Laboratory policy, Alere Triage, C. External Liquid Controls) 3. In a telephone interview at 0955 CDT on 11-13-2019, the laboratory technical consultant confirmed that no IQCP had been developed for cardiac enzyme and D-dimer testing using the Alere Triage analyzer. II. Based on review of laboratory procedures, quality control documentation and staff interview, the laboratory failed to perform quality controls for blood gas testing using the Abbott i-Stat analyzer and CG4+ test cartridge at the required frequency. Findings: 1. Laboratory quality control logs were reviewed. Logs for the i-Stat analyzer and CG4+ test cartridge indicated external quality controls being performed monthly and at test cartridge lot change. In an interview at the site on 10-24-2019, testing person 24 stated that this reflected current laboratory practice. On inquiry he further stated that to his knowledge the laboratory had not developed an individual quality control plan (IQCP) for i-Stat CG4+ testing. 2. In a telephone interview at 1550 CDT on 11-07-2019, the laboratory technical consultant confirmed that no IQCP had been developed for blood gas testing using the Abbott i-Stat analyzer and CG4+ test cartridge. .
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 review of available documentation, confirmed by staff interview, the laboratory technical consultant failed to verify performance characteristics for the Abbott i-Stat chemistry analyzer using the CH4+ test cartridge prior to patient testing. Refer to D 5421.