Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1074317	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Er Quickcare Pl	13030 Livingston Rd Ste 3, Naples, FL	

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	An announced CLIA recertification survey was conducted at ER Quickcare PL on 04 /15/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of record review and interview with Testing Personnel #B, the laboratory failed to verify the quality control manufacturer's recommended range for the Urinalysis (for the Urisys instrument) , Serum HcG (manual testing), Chemistry (for the Triage Meter Pro), and Hematology controls (for the Coulter ACT Diff 2 Hematology Analyzer) for two out of two years (2019-2021). Findings included: Review of Urinalysis, Serum HcG, Chemistry and Hematology quality control records revealed the lack of quality controls records for verification of quality control manufacturer's recommended ranges for the new lot of Kovac (for Urinalysis and Serum HeG), Chemistry controls (CKMB, D Dimer, Troponin and Brain Natriuretic

	peptide) and Hematology controls for two out of two years (2019-2021). Interview on 04/15/2021 at 12:45 PM, Testing Personnel #B stated that the laboratory had discontinued performing verification of quality control manufacturer's recommended ranges because the previous laboratory consultant had told them the laboratory did not have to verify quality control manufacturer's recommended ranges.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the Laboratory Director failed to follow the laboratory's procedure for Quality Assurance (QA) review for 2 (April - December 2019, January - December 2020, and January - March 2021) out of 2 years reviewed. Findings Included: Review of the Laboratory procedure "Lab Staff Job Description Moderate Complexity" revealed " 4. Perform all Quality Assessment activities assigned to this position and document these activities for periodic review by the Laboratory Supervisor and/or the Laboratory Director." Review of laboratory documentation revealed that the Testing Personnel #B was documenting she reviewed all laboratory QA monthly. for 2 (2019 - 2021) out of two years and the Laboratory Director had not documented reviewing QA for 2 (April - December 2019, January - December, and January - March 2021) years. Interview on 04/15/10 at 02:00 PM, the Laboratory Director stated he did not know he was suppposed to review the monthly Quality Assessment activities performed by Testing Personnel #B.