Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1074317	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Er Quickcare Pl	**Street Address, City, State** 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 March 26, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have the two out of seven testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for Mycology and Parasitology specialties in 2 out of 2 years reviewed. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 03/02/2025 revealed the laboratory had seven TP listed (TP#1, TP# 2, TP#3, TP#4, TP#5, TP#6 and TP#7). 2-Review of KOH control log for 2023, 2024 and 2025 revealed that TP#2, TP#6 and TP#7 performed the controls for the testing of reference. 3-Review of American Proficiency Institute (API) PT records for 2023 (first and second event), 2024 (first, and second) and 2025 (1st event) revealed that TP#2 signed all events for the Vaginal Wet Prep, Vaginal Wet Prep (KOH) and Urine Sediment. TP#6 and TP#7 did not participate in the events of reference. 4-During an interview on 03/26/2025 at 01:30 PM, the Consultant confirmed that the laboratory failed to rotate the PT between TP#2, TP#6 and TP#7 for the period of reference.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on laboratory records review and staff interview, the laboratory failed to do competency evaluation for one out of seven Testing Person (TP) Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director (LD) on 03/02/2025 revealed that the LD was Clinical Consultant (CC), Technical Consultant (TC) for Mycology, Chemistry and Hematology specialties and TP#6, the 209 listed 6 more TP (TP#1, TP#2, TP#3, TP#4, TP#5 and TP#7). 2- Review of personnel records revealed that TP#7 that performed the KOH test during 2023 and 2024, did not have record of competency evaluation for those years. 3-During an interview on 03/26/2025 at 2:30 PM, with LD, he confirmed that TP#6 failed to have competency evaluation for 2023 and 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the control material for D-Dimer, Troponin and Creatine Kinase MB (CK-MB) tests on the Quidel Triage for 9 months reviewed from September 2023 to March 2025. Findings included: 1-During the laboratory tour on 03/26/2025 at 11:00 AM, the surveyor found stored in a freezer one open box of Quidel Triage Total 5 Control Product level 1 lot number C4080AN, one unopen box of Quidel Triage Total 5 Control Product level 1 lot number C4087AN and one open box of level 2 with lot number C4089AN. 2-Review of the required storage temperatures as per manufacturer showed a storage requirement in a non-defrosting freezer at -20 Celsius Degrees (C) or colder. 3-Review of the temperature log revealed an acceptable temperature range of -15C or less DEGC. The range does not meet the storage requirements. 4-Review of documented temperature log for the following months: September 2023, May 2024, July 2024, August 2024, September 2024, October 2024, December 2024, January 2025 and March 2025, revealed that the temperature has not reached the requirement of -20 or colder. The freezer temperatures were documented at levels of -14.4 C to -19 C. 5-During an interview on 05/02/2023 at 10:30 PM, Testing Person #1 confirmed that the controls listed above were stored outside of the acceptable range as per manufacturer instructions in the months of reference.