

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1074317	(X3) Date Survey Completed 07/18/2023
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 07/18/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with Testing Personnel #C, the laboratory failed to follow the laboratory's procedure for centrifuging urine sediment specimens at the correct speed and time for two out of two years reviewed (2021 - 2023). The laboratory had performed 2,391 patients urine sedimentation tests from April 16, 2021 to July 18, 2023. Findings included: On 07/18/23 at approximately 9:20 am, observation revealed the laboratory was using a designated centrifuge that did not adjust for time and centrifuge speed when spinning blood and urine specimens. Interview with the Testing Personnel #C at time of observation revealed the centrifuge was used for blood specimens and urine specimens for urine sedimentation testing . Review of the "Operator's Manual Drucker Diagnostics" revealed "General Specifications for the Model 642E Centrifuge... Nominal speed (horizontal): 3380 (=/- 100) RPM " Review of the laboratory's policy "Routine Urinalysis" revealed "If microscopic is warranted, centrifuge urine in the conical tube for 5 minutes." On 0718/2023 at 9:45 AM, Testing Personnel #C confirmed that the centrifuge was being used for blood and urine specimens, but the laboratory used a separate timer that was set at 3 minutes and 30 seconds for urine specimens instead of using the centrifuge timer that was set at 10 minutes for blood specimens.</p>