Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2174805	04/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Virtual Care Center	15740 South Outer Forty Rd, Chesterfield, MO	

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**
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the laboratory director (LD), the laboratory failed to provide a step-by-step procedure for transporting iStat cartridges from the main storage refrigerator to the mobile refrigerator. Findings: 1. Review of the laboratory procedures showed no procedure for step by step instruction in transporting iStat Chem 8 and CG4 cartridges from the main storage refrigerator to the mobile refrigerator to maintain proper storage temperature. 2. Interview with the

	LD on April 19, 2023 at 11:00 AM confirmed the laboratory failed to establish a step-by-step procedure for transporting iStat cartridges from the main storage refrigerator to the mobile refrigerator.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of iStat Chem 8 and CG4 cartridge package insert, lack of temperature logs for the mobile refrigerator and interview with the laboratory director (LD), the laboratory failed to provide documention of proper storage requirements of iStat Chem 8 and CG4 cartridges when transporting in the mobile refrigerator. Findings: 1. Review of Chem 8 and CG4 iStat cartridge package insert states the refrigerated storage is 2 C to 8 C. 2. Lack of temperature logs confirmed no documentation of temperature when cartridges are in the mobile refrigerator. 3. Interview with the LD on April 19, 2023 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documenting temperature for storage of iStat Chem 8 and CG4 cartridges in the mobile refrigerator.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2021, 2022 and 2023 and interview with laboratory director (LD), the LD failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective actions on the 2023 chemistry first event. Findings: 1. Review of the first event of 2023 Chemistry PT records showed a result of 80% for PCO2 with no evaluation to identify corrective action. 2. Interview with LD on April 19, 2023 at 11:00 AM confirmed that the LD failed to ensure review for the 2023 chemistry first PT event.