Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2078851	07/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cardiopulmonary Laboratory	701 S Health Pkwy, Three Rivers, MI	

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
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Manager (LM), the laboratory failed to use sufficient equipment for the i-stat testing it performs for 2 (June 2021 to June 2023) of 2 years. Findings include: 1. An observation on 7/24 /2023 at 9:40 am by the surveyor revealed a printer for the i-stat analyzer in the testing basket. 2. An email conversation on 7/25/2023 at 3:30 pm with the LM revealed the printer for the i-state analyzer is only used for American Proficiency Institute testing, quality control, and calibration verifications. 3. A record review revealed for 2 (06058259 performed on 11/16/2021 and 00302650 performed on 4/10 /2023) patient test results reviewed; the laboratory failed to have a printout copy from the i-STAT analyzer. 4. A email conversation on 7/25/2023 at 3:30 pm with the LM, revealed a lack of instrument printouts to verify patient results that were transcribed to a manual report form and/or transcribed directly into the laboratory information system (LIS) from June 2021 to June 2023.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to retain patient instrument printouts from the i-stat analyzer for 2 (June 2021 to June 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's i-stat records revealed a lack of patient testing documents generated from the i-stat printer. 2. Review of the "i-STAT 1 Analyzer" procedure under "Results" section states the following: "B. Results may be printed through use of the portable printer. "F. All results printed from portable printers must have patient name and identification clearly marked and must be accompanied by reference ranges to aid in result interpretation." 3. An email on 7/25/2023 at 3:30 pm with the LM revealed that patient testing was never printed at the time of testing, so no original documents were retained only the laboratory information system results.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on procedure review and lack of documentation, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems. Findings include: 1. A procedure review revealed the laboratory did not establish a quality assurance policy that would monitor the general, pre-analytic, analytic, and post-analytic systems in the laboratory. Cross reference D3007, D3031, D5291, D5400, D5805. a. The laboratory failed to use sufficient equipment for the i-stat testing. Refer to D3007. b. The laboratory failed to retain patient instrument printouts from the i-stat analyzer. Refer to D3031. c. The laboratory failed to meet applicable analytic system requirements and correct identified problems. Refer to D5401, D5445, and D5445. d. The laboratory failed to indicate the identity of the instrument used (secondary instrument) on the patient test report. Refer to D5805. 2. On July 24, 2023, at 2:10 pm, the surveyor revealed by a lack of documentation that the laboratory had no ongoing review process to monitor an access the laboratory general, pre-analytic, analytic, and post-analytic mechanism.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to establish a test

	procedure for the updated i-STAT cartridge. Refer to D5401. 2. The laboratory failed to ensure the i-STAT individualized quality control plan (IQCP) was updated for the new cartridge (CG8+). Refer to D5445. 3. The laboratory failed to test at least two levels of control material each day of patient testing for the chemistry i-STAT analyzer. Refer to D5447.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to establish a test procedure for the updated i-STAT cartridge for the blood gas testing for 2 (June 2021 to June 2023) of 2 years in use. Findings include: 1. A review of the laboratory's policies and procedures revealed a procedure "i-STAT 1 Analyzer" for use with the i-STAT G3+ cartridge. 2. A record review of the i-STAT Calibration Verification Log" revealed back in June 2023 the CG8+ cartridge was in use. 3. When queried, the LM confirmed that the new cartridge was put into use back in May or June of 2020. 4. An interview on 7/25/2023 at 2:10 pm, the LM confirmed the laboratory had not updated the "i-STAT 1 Analyzer" procedure for the new cartridge.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:
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:

	. Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to test at least two levels of control material each day of patient testing for the chemistry i-STAT analyzer for 2 June 2021 to June 2023) of 2 years reviewed. Findings include: 1. A review of the "i-STAT 1 Analyzer" procedure under the Quality Control section states "The liquid QC is used to verify the functionality of the cartridge lot number in use. Run two levels of chemistry QC for each new lot number or new shipment of i-STAT cartridges." 2. A review revealed for 2 of 2 years the Individualized Quality Control Plan (IQCP) in use was for a different i-STAT cartridge (G3+) not the CG8+. 3. A lack of documentation every day of patient testing for two levels of quality control was not available when queried on 7/25/2023 at 11:33 am. 4. An interview on 7/25/2023 at 11:33 am, the LM confirmed that each day of patient testing the quality control was not performed and documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to indicate the identity of the instrument used (secondary instrument) on the test report for the i-STAT analyzer for 2 (881981 and 06058259) of 2 patient results reviewed from the i-STAT analyzer. Findings include: 1. Record review for 2 (881981 and 06058259) of 2 patient's final reports in the laboratory information system (LIS) revealed the blood gas and pH results were performed on the i-STAT analyzer, the report did not state the instrument of use. 2. When queried on 7/24/2023 at approximately 1:50 pm, the LM was not able to provide the surveyor evidence to show the i-STAT analyzer was the instrument in use for the 2 patients listed above. 3. A interview on July 24, 2023, at 2:10 pm, the LM confirmed the patient final report in the LIS does not include that the tests were performed on the i-STAT analyzer.
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 record review and interview with the Laboratory Manager (LM), the

	Laboratory Director failed to ensure final proficiency testing reports were reviewed for 5 (Chem Core 3rd event 2021, 1st-3rd events 2022, and 1st event 2023) of 5 events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) final proficiency testing records revealed a lack of review by the testing personnel for 5 (Chem Core 3rd event 2021, 1st-3rd events 2022, and 1st event 2023) of 5 events reviewed. 2. An interview on 7/24/2023 at 11:47 am the LM confirmed the testing personnel failed to review the final proficiency testing reports for the events listed above.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to have a qualified Technical Consultant evaluate the competency of testing personnel performing routine chemistry, toxicology, and hematology testing for 4 (Testing Personnel (TP) #1, #4, #5, and #7) of 8 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency assessments revealed for 4 of 8 competency assessments the reviewers performing the evaluations were not qualified as a Technical Consultant or listed on the CMS-209 or part of the cardiopulmonary laboratory as follows: a. TP #1 - 6/14 /2022 and 6/13/2023 assessments the reviewer is not part of the cardiopulmonary laboratory and not listed on the CMS-209. b. TP #4 - 7/2/2021 assessment by TP#7 is not qualified. c. TP #5 - 3/27/2023 assessment by TP#7 is not qualified. d, TP #7 - 4/8 /2023 assessment the reviewer is not part of the cardiopulmonary laboratory and not listed on the CMS-209. 2. The surveyor requested credentials for the reviewers of TP #1 and TP #7, and they are not qualified. TP #7 credentialing revealed they do not qualify as a Technical Consultant. 3. An interview on 7/24/2023 at 10:21 am with the LM, confirmed the above credentialing revealed the qualifications were not met.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a lack of documentation and record review, the laboratory failed to ensure testing personnel were qualified for 1 (Testing Personnel (TP) #4) of 8 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualification documentation for TP #4 listed on the CMS-209 form as performing moderate complexity testing. 2. The surveyor requested qualification documentation for TP #4 to showing they were qualified to perform moderate complexity testing on 7/25/2023 at 10:02 am and it was not made available. 3. The laboratory was provided 7 days to supply documentation and it was not made available.