Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0531694	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Peoria Post Acute And Rehabilitation	13215 N 94th Dr, Peoria, AZ	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for CG8+ testing performed on the i-Stat analyzer and interview with the technical consultant, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory performs CG8+ testing on the I-Stat analyzer, with an approximate annual test volume of 2,500. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification for CG8+ testing

	at least once every six months during 2021 and 2022, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. Calibration verification documentation reviewed during the survey conducted on 11/17/22 indicated the lab performed a calibration verification on 7/27/2020, with the next calibration verification performed on 9/13/2021. 4. The technical consultant interviewed on 11/17 /22 at 2:45pm acknowledged that a calibration verification was not performed every 6 months on the I-stat analyzer as required for CG8+ testing.
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: Based on lack of Quality Control (QC) documentation and interview with the technical consultant, the laboratory failed to perform and document control procedures using the number and frequency established by the laboratory for testing performed in the specialties of Hematology and Chemistry. Findings include: 1. The laboratory began patient testing using the CG8+ test cartridge on the i-Stat analyzer on September 8, 2020. The CG8+ test cartridge includes the following analytes: Sodium, Potassium, Ionized Calcium, Glucose, Hematocrit, Hemoglobin, pH, pCO2, pO2, TCO2, HCO3, Base Excess, and SO2. An Individualized Quality Control Plan (IQCP) was established and approved by the laboratory for this test on 07/28/2020. 2. The IQCP reviewed during the survey for the CG8+ test indicated that two levels of external Quality Control (QC) will be performed at least monthly and for each new lot or shipment of test cartridges. 3. QC records reviewed during the survey revealed the laboratory failed to perform two levels of QC at least monthly as evidenced by: - QC was performed on 10/26/20 and not again until 12/04/20 - QC was performed on 12/04 /20 and not again until 2/02/21 - QC was performed on 2/17/21 and not again until 4 /16/21 - QC was performed on 4/16/21 and not again until 5/28/21 - QC was performed on 6/18/21 and not again until 9/13/21 - QC was performed on 9/13/21 and not again until 11/30/21 - QC was performed on 12/30/21 and not again until 2/03/22 - QC was performed on 4/13/22 and not again until 6/28/22 - QC was performed on 6 /28/22 and not again until 8/15/22 4. The technical consultant interviewed on 11/17/22 at 3:10pm confirmed the laboratory failed to perform QC with the frequency established by the laboratory in the IQCP.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of established Quality Assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic laboratory systems. Findings include: 1. The laboratory's established QA policy reviewed during the survey indicates the laboratory will perform and document quarterly QA reports. 2. No QA documentation was provided for review during the survey conducted on 11/17/2022 to indicate the laboratory performed and documented QA activities on a quarterly basis from January through November 17, 2022, to monitor, assess and, when indicated, correct problems identified in the analytic laboratory systems. 3. The technical consultant interviewed on 11/17/22 at 3:30pm confirmed the laboratory failed to provide documentation of quarterly QA reports to monitor, assess and correct problems identified with the analytic laboratory systems.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of patient test results in the laboratory's Electronic Medical Record (EMR), review of patient test records and interview with the technical consultant, the laboratory failed to ensure that test results are accurately and reliably sent from the point of data entry to the final report destination. Findings include: 1. The laboratory performs testing on the i-Stat analyzer in the specialties of Chemistry and Hematology, with an approximate annual test volume of 2,500. 2. It is the practice of the laboratory to tape the instrument printout to a worksheet titled "Arterial Blood Gas", and then scan the worksheet into the patient's Electronic Medical Record (EMR). The laboratory utilizes the EMR as the final report destination for results of laboratory testing. 3. Two out of four patient test results reviewed during the survey for CG8+ testing were missing from the patient's EMR, including patient #12689 from 3/06/22 at 05:46 and patient #11657 from 4/20/21 at 10:05. 4. The technical consultant interviewed during the survey on 11/17/22 at 2:30pm confirmed the test results indicated above were not reliably sent to the EMR.
D6020	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 the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of Quality Control documentation from testing performed on the i-Stat analyzer, the laboratory director failed to ensure that the quality control program is maintained to assure the quality of laboratory services provided. See D5445 for findings.
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 review of quality assessment policies and documentation, the laboratory director failed to ensure that the quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5791 for findings.