Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0926253	03/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
South Mountain Post Acute	8008 South Jesse Owens Parkway, Phoenix, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on lack of patient test reports for review, review of the laboratory's established procedure for i-Stat test reporting and interview with the technical consultant, the laboratory failed to retain i-Stat test reports for at least 2 years after the date of reporting. Findings include: 1. The laboratory began patient testing on the i-Stat analyzer on September 16, 2020 in the sub-specialties of Routine Chemistry and Hematology, with an approximate annual test volume of 900. The laboratory performs the Chem8+ test and the CG4+ test (for Arterial Blood Gas). 2. The laboratory's established test procedure for testing performed on the i-Stat analyzer states, "Follow handheld prompts. Enter Operator ID number as assigned to each user. Enter Patient ID number...Attach printout to Lab Report Form, verifying that patient ID numbers match. Results will be filed into patient (EMR) record under tab of labs." 3. According to the established procedure indicated above, the testing personnel must attach the i-Stat instrument printout to a form titled, "Laboratory Report Form i-Stat Point of Care" and manually fill in the remaining information on the form. The form includes the reference ranges for Chem8+ and CG4+ analytes, and an area to manually write in the following information: Patient Name, DOB, Patient ID#, Test Ordered, Order Attached (Y/N), Ordered By, Date Drawn, Time Drawn, Drawn By, Puncture Site, Modified Allen's Test (Pos/Neg), Critical Results (Y/N), Results Reported To, Reported Via (In person/phone), Time Reported, Comments, Device, Pt RR, SpO2, FIO2, Settings, and RT Signature. 4. No evidence of the 'Laboratory Report Form i-Stat Point of Care' was provided for review during the survey

	performed on March 30, 2023 for all i-Stat test results which were performed and reported prior to March 31, 2022. 5. The technical consultant interviewed on March 30, 2023 at 10:45am stated that the 'Laboratory Report Form i-Stat Point of Care' for each patient tested prior to 3/31/2022 was thrown away by laboratory staff and not retained for at least 2 years after the date of reporting.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of i-Stat instrument printouts, i-Stat test procedures and interview with the technical consultant, the laboratory failed to follow established policies and procedures to ensure positive identification of the patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. The laboratory began patient testing on the i-Stat analyzer on September 16, 2020 in the sub-specialties of Routine Chemistry and Hematology, with an approximate annual test volume of 900. The laboratory performs the Chem8+ test and the CG4+ test (for Arterial Blood Gas). 2. The laboratory's established test procedure for testing performed on the i-Stat analyzer states, "Follow handheld prompts. Enter Operator ID number as assigned to each user. Enter Patient ID number...Attach printout to Lab Report Form, verifying that patient ID numbers match." 3. Instrument printouts reviewed and printed from the i-Stat analyzer during the survey for two out of two patients, Patient# 8522 from 6-25-2021 and Patient# 5056 from 10-05-2021, revealed each patient was tested for both Chem8+ and Arterial Blood Gas (ABG) testing. 4. The patient ID numbers entered into the i-Stat as indicated above (#8522 and #5056) were not valid patient ID numbers or the patient ID's were incorrect, as these patient ID numbers could not be traced back to specific patients during the survey. 5. The laboratory failed to follow established policies and procedures to maintain positive patient identification on patient specimens throughout the entire testing process on the i-Stat analyzer. 6. The technical consultant interviewed on March 30 , 2023 at 11: 00am confirmed that the laboratory failed to follow established policies and procedures related to the i-Stat analyzer to ensure positive patient identification throughout the entire testing process.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview with the technical consultant, the laboratory's QA processes failed to include a review

	of the effectiveness of corrective actions taken to resolve problems found in the general laboratory systems. Findings include: 1. The laboratory began patient testing on the i-Stat analyzer on September 16, 2020 in the sub-specialties of Routine Chemistry and Hematology, with an approximate annual test volume of 900. The laboratory performs the Chem8+ test and the CG4+ test (for Arterial Blood Gas). 2. The laboratory failed to follow established policies and procedures to maintain positive patient identification on patient specimens throughout the entire testing process on the i-Stat analyzer. See D5203 for specific findings. 3. The laboratory performs a quarterly QA chart audit to ensure correct and accurate test result information is maintained in the EMR. One out of four patient test records audited during the April - June 2021 quarterly QA review was identified by the laboratory as having an incorrect Patient ID# (8522). 4. The quarterly QA review documentation from April - June 2021 stated, "Patient #8522 is an unknown number. Operator ID is unknown. TP-1 to investigate." 5. The laboratory failed to provide evidence of a review of the effectiveness of the corrective action taken to resolve problems identified with the specimen identification error for Patient #8522, including but not limited to, a revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general systems quality assessment reviews with appropriate staff. 6. The technical consultant interviewed on March 30, 2023 at 12: 14pm confirmed that the laboratory's QA processes failed to include a review of the effectiveness of the corrective actions taken for the specimen identification error indicated above.
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 lack of temperature and humidity documentation for review and interview with the technical consultant, the laboratory failed to monitor and document the room temperature, refrigerator and ambient humidity that is essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting for testing performed on the i-Stat analyzer. Findings include: 1. The laboratory began patient testing on the i-Stat analyzer on September 16, 2020 in the sub-specialties of Routine Chemistry and Hematology, with an approximate annual test volume of 900. The laboratory performs the Chem8+ test and the CG4+ test (for Arterial Blood Gas). 2. The laboratory failed to monitor and document the humidity of the room where i-Stat testing occurs and testing reagents are stored from January 2021 through June 2021. The manufacturer's ambient humidity requirement for the i-Stat analyzer is 0 - 90%. 3. The laboratory failed to monitor and document the temperature of the room where i-Stat testing occurs and testing reagents are stored from January 2021 through June 2021. The manufacturer's operating temperature requirement for the i-Stat analyzer is 61 - 86 F. 4. The laboratory failed to monitor and document the temperature of the refrigerator where the i-Stat testing reagents are stored from January 2021 through June 2021. The manufacturer's storage requirement for

	cartridges used on the i-Stat analyzer is 35 - 46 F. 5. The technical consultant interviewed on March 30, 2023 at 11:55am confirmed that the laboratory failed to produce evidence of temperature and humidity documentation from January 2021 through June 2021 for the room where testing occurs and the refrigerator where test supplies are stored, as indicated above.
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 on September 16, 2020 using the CG8+ test cartridge and the CG4+ cartridge on the i-Stat analyzer, with an approximate annual test volume of 900. The CG8+ test cartridge includes the following analytes: Sodium, Potassium, Ionized Calcium, Glucose, Hematocrit, Hemoglobin, pH, pCO2, pO2, TCO2, HCO3, Base Excess, and SO2. The CG4+ test cartridge includes the following analytes: pH, pCO2, pO2, BE, HCO3, tCO2, SO2 and Lactate. An Individualized Quality Control Plan (IQCP) was established and approved by the laboratory for each test. 2. The established IQCP's reviewed during the survey for the Chem8+ test and the CG4+ 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 for the Chem8+ test revealed the laboratory failed to perform two levels of external QC at least monthly as evidenced by: - QC was performed on 10/20/20 and not again until 11/30/20 - QC was performed on 11/30/20 and not again until 12/31/20 - QC was performed on 1/29/21 and not again until 3/10 /21 - QC was performed on 4/14/21 and not again until 5/31/21 - QC was performed on 6/17/21 and not again until 7/31/21 - QC was performed on 8/05/22 and not again until 9/23/22 - QC was performed on 9/23/22 and not again until 11/18/22 - QC was performed on 12/12/22 and not again until 1/31/23 4. QC records reviewed during the survey for the CG4+ test revealed the laboratory failed to perform two levels of external QC at least monthly as evidenced by: - QC was performed on 10/20/20 and not again until 11/30/20 - QC was performed on 4/14/21 and not again until 5/31/21 - QC was performed on 6/17/21 and not again until 7/31/21 - QC was performed on 11 /01/21 and not again until 12/08/21 - QC was performed on 12/08/21 and not again until 01/31/22 - QC was performed on 3/15/22 and not again until 5/26/22 - QC was performed on 5/26/22 and not again until 8/05/22 - QC was performed on 8/05/22 and not again until 9/19/22 - QC was performed on 9/19/22 and not again until 11/18/22 - QC was performed on 12/12/22 and not again until 01/31/23 5. The technical

	consultant interviewed on March 30, 2023 at 11:40am confirmed the laboratory failed to perform two levels of external QC with the frequency established by the laboratory in the IQCP for the Chem8+ test and the CG4+ test.
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 Quality Assessment (QA) documentation, analytic test records, laboratory policies and procedures and interview with the technical consultant, the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of Quality Control (QC) records for testing performed in the specialties of Chemistry and Hematology. See D5445 for findings. 2. The technical consultant interviewed on March 30, 2023 at 12:17pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the frequency of quality control performance on the i-Stat analyzer.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview with the technical consultant, the laboratory's QA processes failed to include a review of the effectiveness of corrective actions taken to resolve problems found in the postanalytic systems. Findings include: 1. The laboratory began patient testing on the i-Stat analyzer on September 16, 2020 in the sub-specialties of Routine Chemistry and Hematology, with an approximate annual test volume of 900. The laboratory performs the Chem8+ test and the CG4+ test (for Arterial Blood Gas). 2. The laboratory failed to retain i-Stat test reports maintained in the EMR for a period of at least 2 years from the date the test was performed. See D3041 for specific findings. 3. The laboratory performs a quarterly QA chart audit to ensure correct and accurate test result information is maintained in the EMR. Three out of four patient test records (Pt# 10787, 10289 and 10817) audited during the April - June 2021 quarterly QA review were not scanned into the patient's EMR as required by laboratory policy. 4. The quarterly QA review documentation from April - June 2021 stated, "A nurse 'cleaned' the i-Stat binders and discarded all hard copies of i-Stat reports. (TP-1) will determine which reports were not yet scanned into the EHR and recreate the reports. Binders

	will be kept in a safer place." 5. The laboratory failed to provide evidence of a review of the effectiveness of the corrective action taken to resolve problems identified with missing test report documentation, including but not limited to, a revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. 6. The technical consultant interviewed on March 30, 2023 at 12:15pm confirmed that the laboratory's QA processes failed to include a review of the effectiveness of the corrective actions taken for missing test report documentation as indicated above.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on facility personnel interviews on March 30, 2023, quality control record review, quality assessment protocols and record review, the laboratory director failed to ensure that quality control and quality assessment programs were maintained to identify failures in quality as they occur. See D5293, D5445, D5791 and D5893 for findings.