Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2135367	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Surprise Health & Rehabilitation Center	14660 W Parkwood Dr, Surprise, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2022 and interview with the technical consultant, the laboratory failed to test PT samples by testing personnel who routinely perform patient testing in the laboratory. Findings include: 1. The laboratory participates in PT for the specialty of Chemistry, which includes 3 testing events per calendar year consisting of 5 samples each. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on November 17, 2022 listed nine testing personnel who routinely perform patient testing. 3. Review of the laboratory's PT records from 2022 indicated the same testing personnel tested all of the PT samples for each of the 3 testing events during 2022. 4. The technical consultant interviewed during the survey on 11/17/22 at approximately 10:00am confirmed that the same testing personnel had tested all the PT samples during 2022, as indicated above.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the technical consultant the laboratory failed to have a written or electronic request for

	patient testing for one out of five patient records reviewed during the survey. Findings include: 1. The laboratory performs testing on the i-Stat analyzer using the CG8+ and CG4+ test cartridges under the specialties of Chemistry and Hematology, with an approximate annual test volume of 2,500. 2. No written or electronic request for CG8+ testing was presented for review for one out of five patient records reviewed during the survey, patient# 3071 tested on 8/14/21 at 11:54. 3. The technical consultant interviewed on 11/17/22 at 10:55am confirmed that the laboratory did not have an electronic or written test requisition for testing that was performed on the patient indicated above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct inspection of i-Stat test cartridges and interview with the testing personnel, the laboratory failed to label CG8+ test cartridges with the correct open expiration date. Findings include: 1. The laboratory began patient testing using the CG8+ test cartridge on the i-Stat analyzer in November 2020, with continued use through the date of the survey performed on 11/17/2022. The CG8+ test cartridge includes the following analytes: Sodium, Potassium, Ionized Calcium, Glucose, Hematocrit, Hemoglobin, pH, pCO2, pO2, TCO2, HCO3, Base Excess, and SO2. 2. Review of the laboratory's established policy and test manufacturer's package insert indicates CG8+ test cartridges may be stored at room temperature for 2 months. 3. During the survey performed on 11/17/2022, direct inspection of the CG8+ test cartridges stored at room temperature and used by the laboratory at the time of the survey revealed a hand-written expiration date of 2/16/2023 (cartridge lot# W22236A, expiration date 4-23-23). 4. The testing personnel interviewed on 11/17/22 at 12:10pm confirmed that the laboratory failed to document the correct expiration date on CG8+ test cartridges that were stored at room temperature and in use at the time of the survey. 5. The laboratory's approximate annual test volume is 2,500.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance specification documentation for the CG4+ cartridge performed on the i-Stat analyzer and interview with the technical consultant, the

	laboratory failed to verify the performance characteristics for the instrument including accuracy, precision, reportable range and reference range prior to reporting patient test results. Findings include: 1. The laboratory used the CG4+ test cartridge on the i-Stat analyzer from December 2021 through September 2022. The CG4+ panel includes the following analytes: Lactate, pH, pCO2, pO2, TCO2, HCO3, Base Excess (BE) and SO2. 2. During the survey conducted on 11/17/22, review of the performance characteristic documentation for the CG4+ test indicated the laboratory failed to verify the performance characteristics prior to reporting patient test results. The documentation presented for review was approved on 11/08/22. 3. The technical consultant interviewed on 11/17/22 at 10:20am confirmed the laboratory began testing the CG4+ cartridge on the i-Stat analyzer in December 2021, however the verification of performance characteristics was not performed and approved until 11/08/22. The number of patient tests performed on the analyzer using the CG4+ test cartridge could not be determined at the time of the survey.
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 as required for testing performed in the specialties of Hematology and Chemistry. Findings include: A1. The laboratory used the CG4+ test cartridge on the i-Stat analyzer from December 2021 through September 2022. The CG4+ panel includes the following analytes: Lactate, pH, pCO2, pO2, TCO2, HCO3, Base Excess (BE) and SO2. A2. No daily QC documentation for CG4+ testing was provided for review during the survey from the time period of December 1, 2020 through September 30, 2022, to indicate the laboratory performed at least two levels of control material of different concentrations each day of patient testing, as required. The laboratory had not established an Individualized Quality Control Plan (IQCP) for this test until November 8, 2022. A3. The technical consultant interviewed during the survey on 11/17/22 at approximately 11:05am confirmed the laboratory did not perform and document external controls each day of patient testing during the time period indicated above. B1. The laboratory began patient testing using the CG8+ test cartridge on the i-Stat analyzer in November 2020, with continued use through the date of the survey performed on 11/17/2022. 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 IQCP was established and approved by the laboratory for this test on 10/07/2020. B2. 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. B3. 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 9/21/21 and not again until 11/17 /21 - QC was performed on 11/17/21 and not again until 2/11/22 - QC was performed on 4/27/22 and not again until 6/28/22 - QC was performed on 9/05/22 and not again until 10/22/22 B4. The technical consultant interviewed on 11/17/22 at 11:20am confirmed the laboratory failed to perform QC with the frequency established by the laboratory in the IQCP.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of i-Stat test records and interview with the technical consultant, the laboratory failed to follow established policies in place to positively identify each testing personnel who performs testing on the i-Stat analyzer. Findings include: 1. The i-Stat instrument printouts indicate unique operator ID numbers dependent on information entered into the analyzer by the individual performing the test. 2. The laboratory's established testing procedure titled, "Blood Gas CG8+ - Abbott iStat" states, "Enter Operator ID number as assigned to each user." 3. Six out of six i-Stat test records reviewed during the survey were either missing the operator ID or the operator ID was entered incorrectly. 4. The technical consultant interviewed on 11/17 /22 at 11:50am acknowledged that the testing personnel were not consistently and accurately entering their unique Operator ID into the i-Stat analyzer as instructed in laboratory policy.
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. 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 verification of performance specification documentation for the CG4+ test prior to patient testing, for

	testing performed in the specialty of Chemistry. See D5421 for findings. 3. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with incorrect expiration dates hand-written on CG8+ test cartridges for testing performed in the specialties of Chemistry and Hematology. See D5415 for findings. 4. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with incorrect or missing Operator ID's used by testing personnel for testing performed on the i-Stat analyzer. See D5787 for findings. 5. The technical consultant interviewed on 11/17/22 at 12:20pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the analytic 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. Three out of six patient test results reviewed during the survey for CG8+ testing were missing from the patient's EMR, including patient #3963 from 4 /06/22 at 23:39, patient #3071 from 8/14/21 at 11:54 and patient #2656 from 5/31/21 at 08:46. 4. The technical consultant interviewed during the survey on 11/17/22 at 11: 45am confirmed the test results indicated above were not reliably sent to the EMR.
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 review of a patient test report for testing performed on the i-Stat analyzer and interview with the technical consultant, the laboratory's test report failed to indicate the test performed. Findings include: 1. The laboratory performs testing on the i-Stat analyzer using the CG8+ test cartridge which includes the following analytes: Sodium, Potassium, Ionized Calcium, Glucose, Hematocrit, Hemoglobin, pH, pCO2, pO2, TCO2, HCO3, Base Excess, and SO2. The laboratory's approximate annual test volume is 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 Electronic Medical Record. 3. One out of five test reports reviewed during the survey for patient# 2656 (D.V.) from testing performed on 5/31/2021 at 08: 46 failed to list the analytes tested. The instrument printout taped to the worksheet failed to include all analyte names except pH. 4. The technical consultant interviewed on 11/17/22 at 11:37am confirmed that the test report indicated above was missing the name of each analyte tested, with the exception of pH.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) documentation and policies and interview with the technical consultant, the laboratory's established QA policies and procedures failed to identify and correct problems identified in the postanalytic systems. Findings include: 1. It is the practice of the laboratory to perform and document audits on 5 patient charts selected at random at least twice annually to detect errors in the reporting of i-Stat test results. 2. The post-analytic QA documentation presented for review from December 2020 through the date of the survey conducted on 11/17/22 was not effective at identifying and correcting errors found in the post-analytic systems. See D5801 and D5805 for specific findings related to the post-analytic systems. 3. The technical consultant interviewed on 11/17/22 at 12: 25pm confirmed the laboratory's established QA processes failed to identify and correct problems found with the postanalytic systems.
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

	established with the required frequency and 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 and D5891 for findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of four out of four testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for four out of four testing personnel who perform patient testing on the I-Stat analyzer. 2. The facility personnel interviewed on 11/17/22 at 9:47am confirmed that the laboratory failed to provide documentation of a semiannual competency evaluation for the four testing personnel indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review from 2022 and interview with the technical consultant, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on November 17, 2022, no annual competency evaluation documentation from 2022 was presented for

	review for two out of two testing personnel who began testing on the i-Stat analyzer on 10/31/21. 2. At 9:50am on 11/17/22, the technical consultant confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2022 for the two testing personnel indicated above.