| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D2135367 | 04/29/2025 |
| **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 |
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| **D5463** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(7)(g)<br><br>(d)(7) Over time, rotate control material testing among all operators who perform the test.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control (QC) records for testing performed on the i-Stat analyzer and interview with the technical consultant (TC-1), the laboratory failed to rotate control material testing among all operators who perform patient testing on the i-Stat from January 4, 2023 through April 4, 2025. Findings include: 1. The laboratory performs patient testing using the i-Stat under the specialties of Chemistry and Hematology with an annual test volume of 4,416. It is the practice of the laboratory to perform two levels of control material with each new lot or shipment of test cartridges. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on 4/29/25 listed 15 testing personnel who routinely perform patient testing. 3. QC records for the i-Stat analyzer reviewed from 1/04/23 through 4/4/25 indicated the same testing personnel performed QC activities on 47 out of 47 days during that time period. 4. The TC-1 interviewed on 4/29/25 at 1:01 PM confirmed the laboratory failed to rotate quality control testing among all operators who perform patient testing. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>(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 |

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| | who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of i-Stat test records and interview with the technical consultant (TC-1), the laboratory failed to maintain an information or record system to identify five out of fifteen testing personnel who perform testing on the i-Stat analyzer. Findings include: 1. The laboratory maintains a roster to identify the names and unique ID numbers of testing personnel who perform testing on the i-Stat analyzer. The unique ID number is entered into the i-Stat analyzer by each testing personnel each time testing is performed. 2. Review of the roster revealed five out of fifteen testing personnel lacked an assigned unique ID number. 3. The TC-1 interviewed on 4/29/25 at 1:16 PM acknowledged that five out of fifteen testing personnel who perform testing on the i-Stat analyzer were missing assigned ID numbers. 4. The laboratory performs testing in the specialties of Chemistry and Hematology with a reported annual test volume of 4,416. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Thereafter, evaluations must be performed at least annually<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of competency evaluation documentation from 2024 and interview with the Technical Consultant (TC-1), the technical consultant failed to evaluate and document the performance of one out of five individuals responsible for moderate complexity testing at least annually during 2024. Findings include: 1. No annual competency evaluation documentation from 2024 was presented for review for one out of five testing personnel (TP-5) who perform testing on the i-Stat analyzer in the specialties of Chemistry and Hematology. 2. The TC-1 interviewed on 4/29/25 at 1:06 PM confirmed the technical consultant failed to evaluate and document the performance of TP-5 at least annually during 2024. |