Form Approved
OMB No. 0938-0391

| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number | (X3) Date Survey Completed |
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| | 29D2198726 | 08/21/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Comprehensive Surgical Care Of Reno-Tahoe,Llc | 5443 Kietzke Lane Suite 110, Reno, NV | |

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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| **D0000** | This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 21, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the the Individualized Quality Control Plan (IQCP), a review of the laboratory's control logs, a review of the i-Stat print outs, a review of patient test results, and an interview with the technical consultant, the laboratory failed to perform quality control (QC) for the Activated Clotting Time (ACT) testing on the i-Stat as directed to ensure accurate test performance. Findings include: 1. The director approved IQCP plan for ACT testing on the i-Stat indicated that two levels of an external quality control were to be run with "each new lot, each new shipment, every 30 days after the lot/shipment is in use, and after any system maintenance and |

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| | software upgrades (CLEW)." The laboratory failed to document any QC results on the control logs between February 29, 2024 and August 20, 2024. 2. A review of the IQCP for ACT testing on the i-Stat found that the initial IQCP studies were performed between January 25, 2024 through March 6, 2024. 3. A review of the laboratory control logs, found control lots 261161 (Level 1) and 271160 (Level 2), and cartridge lot R23349 were used between January 25, 2024 and February 29, 2024. IQCP QC results between February 29, 2024 and March 6, 2024 were not documented on the control logs. 4. Control results for control lots 261165 (Level 1) and 271165 (Level 2), and cartridge lot R24089 were documented on August 20, 2024. 5. A review of the i-Stat print outs from March 2024 through May 2024, found that there were no print outs available for controls after March 6, 2024. The cartridge lot number documented on the i-Stat print out was 460R233190181. The remaining print outs were for electronic simulator runs on March 22, 2024 and May 15, 2024. 6. A review of patient results found that patients had been tested on May 15, 2024 and June 12, 2024, using cartridge lot 436R233490181. No control results were documented on these days or for the initial use of cartridge lot 436R233490181. 7. These findings were confirmed in an interview with the technical consultant on August 21, 2024 at approximately 11: 30 AM. The laboratory performs approximately 600 hematology tests annually. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's "Environmental Temperature & Humidity" logs and an interview with the technical consultant, the laboratory failed to perform and document corrective action when the room temperature and humidity results were out of the acceptable range. Findings include: 1. A review of the laboratory's "Environmental Temperature & Humidity" logs from May 2024 through June 2024 found that the laboratory failed to document corrective action when the humidity was outside of the acceptable range of 20-60% for 14 days out of 22 working days in May 2024. 2. An interview with the technical consultant on August 21, 2024 at approximately 11:00 AM, confirmed these findings. The laboratory performs approximately 600 hematology tests annually. |
| **D5800** | POSTANALYTIC SYSTEMS<br>CFR(s): 493.1290<br><br>Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. |

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| | 1299 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on the number and severity of the deficiency cited herein, the Condition: Postanalytic Systems was not met. The laboratory failed to ensure that patient reports were generated that contained all relevant reporting information and were readily identifiable and accessible. Findings include: The laboratory failed to ensure that reports were generated from patient result data that included two patient identifiers, the name and address of the laboratory that performed the testing, specimen source, and the disposition of unacceptable specimens. (Refer to D5805) The laboratory failed to ensure that reports were generated from patient result data that included reference intervals or normal values. (Refer to D5807) The laboratory failed to ensure that reports were generated from patient result data that correctly identified and documented the reporting of critical values to the ordering physician or other authorized person (Refer to D5813) The laboratory failed to ensure that reports generated from patient result data were readily identifiable and accessible. (D5819) |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the director approved laboratory policies, a review of patient electronic health records, patient result data, an email from the technical consultant, and an interview with the laboratory manager, the laboratory failed to ensure that patient reports were generated that included two patient identifiers, the name and address of the laboratory, the specimen source, and disposition of unacceptable specimens. Findings include: 1. On the date of survey, August 21, 2024, the laboratory was unable to provide either physical or electronic patient reports for the two patients tested on May 15, 2024 and June 12, 2024. The only test records available were the i-Stat print outs. 2. The technical consultant provided a "Patient Laboratory Result Form" and the "Review of Results-Manual" policy via email on August 23, 2024. The laboratory failed to enter the patient data onto this form and scan it into the electronic health records of the patients as directed by the "Review of Results-Manual" procedure. 3. A review of the director approved procedure titled "Review of Results - Manual" indicated that "The operator will enter laboratory results onto the official test report either by direct observation of the test results or by transferring results from a results log or instrument printout. The patient report will then be scanned into the Electronic Health Record that is being used." 4. The i-Stat print outs of the patient data included only the patient medical record number (MRN), the date the test was performed, and the test results. The print outs failed to include two patient identifiers, the name and address of the laboratory performing the testing, the specimen source, and the disposition of any unacceptable specimens. 5. The |

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| | laboratory manager confirmed these findings in an interview on August 21, 2024 at approximately 11:30 AM. The laboratory performs approximately 600 hematology tests annually. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of patient electronic health records, patient result data, and an interview with the laboratory manager, the laboratory failed to ensure that patient reports were generated that included reference intervals or normal patient values. Findings include: 1. On the date of survey, August 21, 2024, the laboratory was unable to provide either physical or electronic patient reports for the two patients tested on May 15, 2024 and June 12, 2024. The only test records available were the i-Stat print outs. 2. The i-Stat print outs of the patient data reported only the patient results. The print outs failed to include reference intervals or normal ranges for the results. 3. The laboratory manager confirmed these findings in an interview on August 21, 2024 at approximately 11:30 AM. The laboratory performs approximately 600 hematology tests annually. |
| **D5813** | TEST REPORT<br>CFR(s): 493.1291(g)<br><br>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the director approved laboratory policies, a review of patient electronic health records, patient result data, an email from the technical consultant, and an interview with the laboratory manager, the laboratory failed to ensure that critical values were identified and reported appropriately. Findings include: 1. On the date of survey, August 21, 2024, the laboratory was unable to provide either physical or electronic patient reports for the two patients tested on May 15, 2024 and June 12, 2024. The only test records available were the i-Stat print outs. 2. The laboratory manager confirmed that these results were not entered into the patients' electronic health records, in an interview on August 21, 2024 at approximately 11:30 AM. 3. The i-Stat print outs of the patient data indicated only the patient results. The patient results for activated clotting time (ACT) were 223 seconds, 239 seconds, and 256 seconds. 4. The technical consultant provided a "Critical Value" policy via email on August 23, 2024. This policy indicated that the low critical value for ACT was 50-1000 seconds and the high critical value for ACT was 50-562 seconds. The policy also indicates that critical values "must be forwarded to the ordering physician, attending nurse or designated staff member in an expedient manner for immediate attention." 5. It could not be determined using the i-Stat print outs if these patient results had been identified and reported as critical values. The laboratory performs approximately 600 hematology tests annually. |

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| **D5819** | TEST REPORT<br>CFR(s): 493.1291(j)<br><br>All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of patient electronic health records, patient result data, and an interview with the laboratory manager, the laboratory failed to ensure that patient reports were maintained in a manner that allowed for identification and accessibility. Findings include: 1. On the date of survey, August 21, 2024, the laboratory was unable to provide either physical or electronic patient reports for the two patients tested on May 15, 2024 and June 12, 2024. The only test records available were the i-Stat print outs. 2. The i-Stat print outs from two results from one patient on May 15, 2024, and one result from a different patient on June 12, 2024, were taped to a single sheet of paper. The patient medical record numbers (MRNs) and test dates were recorded on the print outs. There was no other identifying documentation on the paper. This paper was not included in either patients' electronic health record. 3. The laboratory manager confirmed these findings in an interview on August 21, 2024 at approximately 11:30 AM. The laboratory performs approximately 600 hematology tests annually. Maintain reports for ready ID and accessibility |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's Quality Assurance (QA) policy and an interview with the technical consultant, the laboratory director failed to ensure that the QA program was maintained as indicated in the laboratory director approved policy to detect and correct errors in quality in the postanalytic systems. Findings include: 1. A review of the director approved QA policy found that the following forms were to be used for quality assessment: a. Calendar Checklist b. Monthly Checklist - Analytic c. Proficiency Testing Checklist d. Test Tracking/Result Reporting/Chart Audit Form e. LIS and EMR Accuracy and Result Storage Assessment f. Review of Patient Population Reference Ranges g. General Review Form h. Unexpected event 2. The laboratory was unable to provide any examples or completed copies of these forms at the time of survey on August 21, 2024. These forms were not included with the policy. 3. An interview with the technical consultant on August 21, 2024, at approximately 11:30 AM, found that no Monthly Checklists or other quality assessments had been performed to date. 4. The QA program failed to detect errors in quality regarding patient reports. (Refer to D5800, D5805, D5807, D5813, and D5819) 5. An interview with the technical consultant on August 21, 2024, at approximately 11:30 AM, confirmed these findings. The laboratory performs approximately 600 hematology tests annually. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>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 a review of the laboratory's Quality Assurance (QA) policy and an interview with the technical consultant, the laboratory director failed to ensure that the QA program was maintained as indicated in the laboratory director approved policy to detect and correct errors in quality. Findings include: 1. A review of the director approved QA policy found that the following forms were to be used for quality assessment: a. Calendar Checklist b. Monthly Checklist - Analytic c. Proficiency Testing Checklist d. Test Tracking/Result Reporting/Chart Audit Form e. LIS and EMR Accuracy and Result Storage Assessment f. Review of Patient Population Reference Ranges g. General Review Form h. Unexpected event 2. The laboratory was unable to provide any examples or completed copies of these forms at the time of survey on August 21, 2024. These forms were not included with the policy. 3. An interview with the technical consultant on August 21, 2024, at approximately 11:30 AM, found that no monthly checklists or other quality assessments had been performed to date. 4. The QA program failed to detect errors in quality regarding quality controls not being performed (Refer to D5441) 5. The QA program failed to detect errors in quality regarding patient reports. (Refer to D5800, D5805, D5807, D5813, D5819, and D5891) 6. The QA program failed to detect the lack of corrective action for out of range humidity results in the laboratory environment. (Refer to D5781) 7. An interview with the technical consultant on August 21, 2024, at approximately 11:30 AM, confirmed these findings. The laboratory performs approximately 600 hematology tests annually.