Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1044203	05/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cash Clinical Of Carson City	2310 S Carson Street - 7a, Carson City, 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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on May 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview with the laboratory manager, the laboratory director failed to attest to the routine integration of the PT samples into the patient workload using the laboratory's routine methods. Findings include: 1. A review of the American Proficiency Institute (API) PT attestation forms from the second PT events of 2022 through the first PT events of 2024 found that the director and staff failed to sign the attestation forms for the second and third hematology/coagulation PT events of 2022 and 2023. 2. A review of the API PT attestation forms from the second PT events of 2022 through the first PT events of 2024 found that the director failed to sign the attestation forms for the third chemistry core PT event of 2023, as well as the first hematology/coagulation and chemistry core PT events of 2024. 3. An interview with the laboratory manager on May 21, 2024 at approximately 4:00 PM confirmed these findings. This is a repeat deficiency previously cited at the CLIA recertification survey conducted on February 13, 2018. The laboratory performs approximately 36,500 hematology and chemistry tests per year.

D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: [Facility Administration] record retention was not met. The laboratory failed to retain documentation of quality controls for the chemistry tests performed on the Dimension EXL for the required minimum of two years. Refer to D3031 The laboratory performs approximately 29,500 chemistry tests annually.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records from June 2022 through May 2024, and an interview with laboratory manager, the laboratory failed to retain the quality control records for the Siemens Dimension EXL, chemistry analyzer for the required two years. Findings include: 1. A review of quality control results for the Dimension EXL chemistry analyzer, revealed that the laboratory did not retain the QC records for the following analytes: direct bilirubin (DBI), triglycerides (TGL), calcium, hemoglobin A1C, low density lipoprotein (LDL), total protein (TP) and albumin (ALB) prior to May 2023. 2. A review of quality control results for the Dimension EXL chemistry analyzer, revealed that the laboratory did not retain the QC records for the following analytes: alanine transaminase (ALT), cholesterol (CHOL), creatinine, and glucose prior to June 2023. 3. A review of quality control results for the Dimension EXL chemistry analyzer, revealed that the laboratory did not retain the QC records for the following analytes: alkaline phosphatase (AlpI), carbon dioxide (CO2), aspartate transferase (AST), high density lipoprotein (HDL), sodium, potassium, and chloride prior to July 2023. 4. A review of quality control results for the Dimension EXL chemistry analyzer, revealed that the laboratory did not retain the QC records for the following analytes: blood urea nitrogen (BUN) and total bilirubin (TBI) prior to September 2023. 5. An interview with the laboratory manager during the on-site inspection on May 21, 2024 at approximately 11:30 AM confirmed that the laboratory could not locate the printed QC records and could not retrieve the QC records on the chemistry analyzer.The laboratory manager stated that the records had been purged

	from the analyzer's computer. This is a repeat deficiency previously cited at the CLIA recertification performed on February 11, 2020. The laboratory performs approximately 29,500 chemistry tests annually.
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 a review of the laboratory procedures, a random review of the monthly reports that have been reviewed for accuracy by the laboratory between July 2022 and April 2024, and an interview with the laboratory manager, the laboratory failed to maintain accurate specimen identification throughout the pre-analytical, analytical, and post-analytical stages of testing. Findings include: 1. The laboratory procedure titled, "Procedure for Random Review of Reports", stated that each report will be reviewed to ensure the patient demographics are accurate. 2. A random review of eighteen reports that had been reviewed by the laboratory for accuracy between July 2022 and April 2024 found that the laboratory failed to ensure that the name for patient 44681 was consistent and correct throughout the process. The report for patient number 44681 reviewed by the laboratory in April 2023 contained the following inconsistencies: a. The patient's first name on the review coversheet did not match the doctor's orders or the patient's receipt. b. The patient's last name on the review coversheet did not match the doctor's orders. c. The patient's last name on the doctor's orders did not match the last name on the final report. d. A copy of the patient's driver's license showed the correct name. 3. An interview with the laboratory manager on May 21, 2024 at approximately 4:00 PM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.
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 a random review of eleven patient test requisitions between June 2022 through March 2024, a review of laboratory procedures, and an interview with the laboratory manager, the laboratory failed to obtain provider authorization prior to patient testing. Findings include: 1. A random audit of eleven patient test requisitions between June 2022 through March 2024 revealed that there was no provider authorization on the Self Ordered Test Requisition for patient number 26072 on October 13, 2022. There was a note on the patient receipt stating "Dr. in Mexico." 2. One of eleven patient requisitions reviewed revealed that there was no provider authorization on the Test Requisition completed by Cash Clinical for patient number 11971 on May 26, 2023. There is an ordering physicians name documented, but there is no provider signature or external requisition with provider authorization. 3. One of eleven patient requisitions reviewed revealed that there was no provider authorization

	on the Test Requisition for patient number 42844 on March 15, 2024. There is no ordering physician's name or signature documented. No external requisition with provider authorization could be provided by the laboratory. 4. The laboratory policy titled "Ordering of Tests" states that patient ordered tests must also be ordered by a physician contracted by the laboratory. It also states that a laboratory Test Order Request Form must be completed for all self ordered testing. This form includes a space for the physician's name and signature. 5. The laboratory policy titled Ordering of Tests states that the laboratory must perform tests only at the written request of an authorized person. 6. An interview with the laboratory manager on May 21, 2024 at approximately 4:00 PM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, and an interview with the office manager, the laboratory director failed to ensure that all policies reflected the current testing instrumentation. Findings include: 1. A review of the laboratory's Quality Control procedure found that on page 2, Corrective Action Methods numbers iv. and vi. refer to "Xpand" reagents and the "Xpand" chemistry analyzer. 2. The current chemistry analyzer in use by the laboratory is a Dimension EXL. 3. A phone call with the office manager on June 3, 2024, at approximately 12:30 PM confirmed these findings. The laboratory performs approximately 29,500 chemistry tests annually. This deficiency was previously cited during the CLIA recertification survey performed on April 26, 2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Siemens Dimension EXL Weekly/Monthly Maintenance logs, and an interview with laboratory manager, the laboratory failed to ensure equipment maintenance was performed as required. Findings include: 1. A review of the Weekly/Monthly Maintenance logs from June 2022 to May 2024 revealed that weekly maintenance was not performed for the following weeks of 2023: January 9-13, April 3-7, May 1-5, November 6-10, and November 20-24. 2. A review of the Weekly/Monthly Maintenance logs from June 2022 to May 2024 revealed that weekly maintenance was not performed for the following weeks of 2024: January 1-5, and January 15-19. 3. A review of the Weekly/Monthly Maintenance logs from June 2022 to May 2024 revealed that the monthly maintenance was not performed as follows: a. Clean clot check drain on IMT port and replace IMT pump tubing was not performed

	for the following months: August 2022, January 2023, May 2023, July 2023, November 2023, and February 2024. b. Clean IMT system was not performed for August 2022 and February 2024. c. Clean R1/R2 drain was not performed for April 2023. d. Clean R3 Drain was not performed for the following months: August 2022, January 2023, April 2023, May 2023, July 2023, and February 2024. 4. An interview with the laboratory manager on May 21, 2024 at approximately 11:30 AM confirmed these findings. This is a repeat deficiency previously cited at the CLIA recertification survey performed on February 11, 2020. The laboratory performs approximately 29,500 chemistry tests annually.
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 a review of available quality control (QC) records from May 2023 through May 2024, a review of laboratory procedures, a random review of the laboratory's reports reviewed for quality assurance between July 2022 and April 2024, and an interview with laboratory manager, the laboratory failed to perform and document corrective action for out of range quality controls on the Siemens Dimension EXL, chemistry analyzer. The laboratory also failed to follow their quality assurance procedure to detect and correct errors in quality as they occurred. Findings include: Quality Control: 1. On July 1, 2023 the low control for total protein (TP) was over three standard deviations (3SD) below the accepted target mean. The laboratory failed to document any investigation or corrective action. 2. On November 27, 2023 the high control for blood urea nitrogen (BUN) was over three standard deviations (3SD) above the accepted target mean. The laboratory failed to document any investigation or corrective action. 3. The laboratory quality control procedure states "if 1 control result exceeds +/- 3SD, then patient results may not be reported until the error is investigated, corrected and action taken documented." 4. An interview with the laboratory manager on May 21, 2024 at approximately 11:30 AM confirmed these findings. Quality Assurance: 5. A review of the policy titled Procedure for Random Review of Reports stated that "Each month the office manager/senior lab assistant will retrieve three completed patient reports at random. The original orders will also be retrieved." 6. A random review of eighteen reports reviewed by the laboratory between July 2022 and April 2024 found that patient 1817 had no final report included for the complete metabolic panel (CMP) and complete blood count (CBC) from the October 24, 2022 draw. The raw data could not be compared to the report for accuracy. 7. A random review of eighteen reports reviewed by the laboratory between July 2022 and April 2024 found that patient 32004 had no final report included for the complete metabolic panel (CMP) and complete blood count (CBC) from the July 19, 2022 draw. The raw data could not be compared to the report for accuracy. 8. A random review of eighteen reports reviewed by the laboratory between July 2022 and April 2024 found that the original test requisition for patient 43440 included a order for LDL/HDL ratio. The laboratory failed to detect that no final report including an LDL/HDL ratio had been issued. 9. An interview with the laboratory manager on May 21, 2024 at approximately 11:30 AM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.

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 a random review of eleven patient test reports between June 2022 through March 2024 and an interview with the laboratory manager, the laboratory failed to provide pertinent units of measurement on the test reports. Findings include: 1. A random audit of eleven patient test reports between June 2022 through March 2024 revealed that five of five final Complete Blood Count (CBC) test reports for patients 41455, 34064, 44523, 44681 and 45451 on June 22, 2022, December 22, 2022, April 8, 2023, April 24, 2023 and July 5, 2023, respectively did not contain units of measurements for immature granulocytes (IG-absolute). 2. Three of three final lipid panel test reports for patients 41455, 42061, 43440 on June 22, 2022, August 18, 2022, and January 4, 2023, respectively did not contain units of measurements for low density lipoprotein (ALDL). 3. An interview with the laboratory manager on May 21, 2024 at approximately 4:00 PM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) 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. This STANDARD is not met as evidenced by: Based on a random review of eleven patient test reports between June 2022 through March 2024 and an interview with the laboratory manager, the laboratory failed to provide pertinent reference ranges on the test reports. Findings include: 1. A random audit of eleven patient test reports between June 2022 through March 2024 revealed that five of five final Complete Blood Count (CBC) test reports for patients 41455, 42061, 34064, 44523, and 45451 on June 22, 2022, August 18, 2022 December 22, 2022, April 8, 2023, and July 5, 2023, respectively contained no reference ranges for red cell distribution width standard deviation (RDW-SD). 2. One of eleven final blood urea nitrogen/creatinine (BUN/CREAT) test reports for patient 21093 on January 3, 2023 contained no reference ranges for the BUN/CREAT ratio. 3. An interview with the laboratory manager on May 21, 2024 at approximately 4:00 PM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: [Director] was not met. The director failed to provide adequate management and direction to ensure that tasks were delegated appropriately, proficiency testing results were reviewed, an adequate quality assurance program was in place, and that initial training was approved. Findings include: 1. The laboratory director failed to document delegation of duties to appropriate personnel. Refer to D6004. 2. The laboratory director failed to evaluate all proficiency testing results, including education and non-graded results. Refer to 6018. 3. The laboratory director failed to ensure that an adequate quality assurance program was established and maintained in order to detect errors in quality as they occurred. Refer to D6022. 4. The laboratory director failed to ensure that the initial training of testing personnel was approved prior to patient testing. Refer to D6029. This Condition level deficiency was previously cited during a proficiency testing desk review survey conducted on October 8, 2019.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedures, proficiency testing (PT) attestation forms, monthly report reviews, and an interview with the laboratory manager, the laboratory director failed to document delegation of their duties. Findings include: 1. A review of the laboratory procedures found that "Delegation Letter I," stated that the responsibility of signing as the director designee was originally signed by the director on May 13, 2011. The latest designee signed on January 3, 2018. The latest review of the form by the laboratory director was on January 15, 2019. The current laboratory manager was not included on this form. 2. The laboratory procedure titled, "Procedure for Random Review of Reports," stated that "the reviewed reports will be placed in the lab folder for the laboratory director or designee to review, date, and sign before these reports are filed." 3. A random review of eighteen monthly reports from July 2022 through April 2024 that had been reviewed by the laboratory for accuracy found that beginning in January 2023 the laboratory director failed to sign the monthly report reviews. The only signature line was for the general supervisor, leaving no space for the laboratory director to sign. These reports were signed by the current laboratory manager who did not have any documentation of delegation for this duty. 4. A review of the PT attestation forms from the second PT events of 2022 through

	the first events of 2024 found that the laboratory manger had signed as the director's designee on the first hematology/coagulation event of 2023 and the second chemistry core event of 2023. There was no documentation of delegation for the laboratory manager to perform this duty. 5. An interview with the laboratory manager on May 21, 2024 at approximately 4:00 PM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records from the second events of 2022 through the first events from 2024 and an interview with the laboratory manager, the laboratory director failed to evaluate the laboratory's performance on PT challenges that were not scored. Findings include: 1. A review of the first and second hematology/coagulation events from 2023 found that the laboratory director failed to document a review of the educational and not graded challenges. 2. A review of the first hematology/coagulation event from 2024 found that the laboratory director failed to document a review of the educational and not graded challenges. 3. An interview with the laboratory manager on May 21, 2024 at appoximately 11:30 AM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually.
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 a review of policies and procedures, a random review of patient records, a random review of the reports utilized by the laboratory for the monthly quality review, and an interview with the laboratory manager, the laboratory director failed to ensure that an adequate quality assurance program was established and maintained in order to detect errors as they occurred. Findings include: 1. The laboratory failed to ensure that patient demographics were accurate throughout all documents from the testing and review process. Refer to D5203. 2. The laboratory failed to ensure that all test requests had an authorization by an approved provider. Refer to D5301. 3. The laboratory failed to detect and correct out of range quality controls. Refer to D5791. 4.

	The laboratory failed to include the patient reports in their monthly reviews according to their policy titled, "Procedure for Random Review of Reports," making it impossible to verify that all patient information and results were correct. Refer to D5791. 5. An interview with the laboratory manager on May 21, 2024, at approximately 4:00 PM, confirmed these findings. The laboratory performs approximately 36,500 chemistry and hematology tests annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of training and competency documentation from May 2022 through May 2024, and an interview with the laboratory manager, the laboratory director failed to approve initial training for testing personnel. Findings include: 1. A review of the training and competency documentation found that the laboratory director failed to approve the initial training for two of two new hires during this time period. These testing personnel are identified as four and six on the CMS 209 form. 2. The laboratory manager was the only approval and signature stating that these two personnel were competent to perform patient testing. 3. A review of the laboratory procedures found that "Delegation Letter I," stated that the responsibility of signing as the director designee was originally signed by the director on May 13, 2011. The latest designee signed on January 3, 2018. The latest review of the form by the laboratory director was on January 15, 2019. The current laboratory manager was not included on this form. 4. A review of the training and competency documentation found that the laboratory director failed to document any competencies for one of six personnel before allowing the employee to perform patient testing. This testing personnel is identified as six on the CMS 209 form. 5. An interview with the laboratory manager on May 21, 2024 at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually. This is a repeat deficiency previously cited at the CLIA recertification survey conducted on February 11, 2020.
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 a review of training and competency documentation from May 2022 through May 2024, and an interview with the laboratory manager, the technical consultant

	failed to approve annual competency assessments for testing personnel. Findings include: 1. A review of the training and competency documentation found that the technical consultant failed to approve the annual competency assessment for one of six testing personnel. This person is identified as number one on the CMS 209 form. 2. An interview with the laboratory manager on May 21, 2024 at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 36,500 hematology and chemistry tests annually. This is a repeat deficiency previously cited at the CLIA recertification survey conducted on April 26, 2022.