Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1044203	02/13/2018
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 2/13/18. 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 review of American Proficiency Institute's (API) proficiency testing (PT) documentation and interview with the laboratory supervisor, the testing personnel and 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: A review of the API PT attestation forms from 2016 and 2017 revealed the PT attestation statement forms were not signed by both the laboratory director and testing personnel certifying that PT samples were tested in the same manner as patient specimens for the first and second chemistry events of 2017 and the first hematology event of 2017. The PT attestation forms were not signed by the testing personnel for the third chemistry event of 2017 and the second hematology event of 2017. The laboratory supervisor confirmed the finding during the on-site survey on 2/13/18 at approximately 10:15 AM. The laboratory performs approximately 26,560 chemistry and 6000 hematology tests annually.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's PT documentation and interview with the laboratory supervisor, the laboratory did not test PT samples the same number of times that it routinely tests patient samples. Findings include: A review of the laboratory test reports for the hematology PT samples tested on the Beckman ACT 5 Diff hematology analyzer for the second event of 2017 revealed that Sample PNT-07 was tested four times over a two week span before a complete report was generated. The five PT samples were first tested by personnel #1 on 7/12/17. Sample PNT-07 had no differential results for neutrophils and eosinophils and there was no test report indicating a repeat test for sample PNT-07 on the same day. The laboratory supervisor indicated during the on-site inspection on 2/13/18 at approximately 10:30 AM that patient samples were tested once and may be repeated once for abnormal results after the initial results were reviewed. All five samples were tested again on 7/13/17 by personnel #2 with no indication why all samples were retested. There were no differential results for neutrophils and eosinophils for samples PNT-07 and PNT-08 with this run. Sample PNT-07 was tested twice on 7/26/17 before a complete differential result was reported by the ACT 5 Diff analyzer. The results from the second repeat on 7/26/17 were submitted to API for evaluation of PT. The laboratory performs approximately 6000 hematology tests annually.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on review of the Dimension XPand Plus Procedure Manual, review of the API PT evaluations, and interview with the laboratory supervisor, the procedure for Free Thyroxine and Total PSA which were discontinued in the first quarter of 2016 did not have the date of discontinuance. Findings include: A review of the API PT evaluations revealed that the laboratory had discontinued testing for free thyroxine and free PSA for the first PT event of 2016. The XPand Plus Procedure Manual contained the procedures for free thyroxine and free PSA and these procedures did not have the date of discontinuance. The laboratory supervisor confirmed during the on-site survey on 2/13/18 at approximately 12:00 PM that these two tests were discontinued. The laboratory performs approximately 800 endocrinology tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on review of the Wright Giemsa Stain QC log and interview with the laboratory supervisor, the laboratory used expired solution 3 to stain blood smears. Findings include: The Wright Giemsa QC log listed the lot numbers and expiration dates of the reagents used to stain blood smears for manual review. Solution 3, lot #1700913, was recorded with an expiration date of 1/12/18. Quality control slides were stained using the expired solution on 1/19/18 to 2/06/18. The laboratory supervisor stated during the on-site inspection on 2/13/18 at approximately 2:00 PM that quality control slides were stained when patient blood smears were stained and new stains were on order. The office manager indicated that a more recent shipment of solution 3 with a longer expiration date was received and found the stain under the sink. This bottle of solution 3 had an expiration date of 6/15/18. However, the testing personnel failed to recognize the expiration date on the QC log and continued using the solution without any investigation and corrective actions taken for the use of the expired solution. The laboratory performs approximately 6000 hematology tests annually.
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 the Corrected Report Investigation Form and interview with the laboratory supervisor, the laboratory failed to verify the glucose reference range before changing the range from the previous reference range. Findings include: A review of the Corrected Report Investigation Form dated 7/24/17 indicated that corrected reports were generated for patient samples tested for glucose from 5/01/17 to 7/17/17 due to a reference range change from 74-115 to 74-100 mg/dL. There was no documentation verifying the new reference range. The laboratory supervisor was unable to find documentation of the verification studies for the new reference range for glucose during the on-site survey on 2/13/18. The laboratory performs approximately 25,760 routine chemistry tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on review of laboratory records and interview with the laboratory supervisor, the laboratory did not have a system that twice a year evaluates and defines the relationship between the automated white cell differential count by the ACT 5 Diff hematology analyzer and a manual differential count performed by the testing personnel. Findings include: There were no records that the laboratory performed test result comparisons between an automated white cell differential count and a manual white cell differential count to evaluate and define the relationship. The laboratory supervisor confirmed the finding during the on-site survey on 2/13/18 at approximately 1:30 PM. The laboratory performs approximately 6000 hematology tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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. This STANDARD is not met as evidenced by: Based on review of the Dimension Xpand Plus Daily Maintenance log from 7/01/17 to 10/31/17 and interview with the laboratory supervisor, the laboratory failed to document corrective actions taken for cuvette temperatures exceeding the temperature range established by the manufacturer. Findings include: Cuvette temperatures recorded from 7/01/17 to 10/31/17 exceeded the manufacturer's established range of 36.8 to 37.2 degrees Celsius for 27 days. Corrective action was not taken until 10/31/17 when documentation showed that the cuvette temperature was recalibrated on 10/31/17. The laboratory supervisor confirmed the finding during the on-site survey on 2/13/18 at approximately 11:00 AM. The laboratory performs approximately 25,760 routine chemistry and 800 endocrinology tests annually.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the Corrected Report Investigation Form and interview with the laboratory supervisor, the laboratory failed to maintain duplicates of the original report and the corrected report. Findings include: A review of the Corrected Report Investigation Form revealed that due to a reference range change, corrected reports

	were faxed to doctors with patient samples tested for glucose from 5/01/17 to 7/17/17. The form indicated to "Attach all results to this sheet from analyzer and LabDaq." There were no attachments to the form. The laboratory supervisor was unable to locate the corrected reports for glucose from 5/01/17 to 7/17/17 and evaluate whether the report clearly indicated both the corrected reference range and the fact that the report was a corrected report. The laboratory performs approximately 25,760 routine chemistry tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing Performance Evaluation and review of the Checklist for Corrective Action and interview with the laboratory supervisor, the laboratory director failed to ensure that an approved corrective action plan was followed when there was unacceptable PT performance with a score of 60% for eosinophils for the second hematology event of 2017. Findings include: There was an unacceptable PT performance with a score of 60% for eosinophils for the second hematology event of 2017. The corrective action for the PT failure for samples tested on 7/12/17 stated that the instrument was scheduled to be calibrated on 11/07/17. There were no corrective action steps taken from 7/12/17 to 11/07/17 and there was no evaluation whether patient results had been affected. The investigation into the PT failure did not address why sample PNT-07 was tested four times before a complete white cell differential was reported. There was no documented laboratory director review of the PT evaluation and corrective action checklist. The laboratory supervisor confirmed the finding during the on-site survey on 2/13/18 at approximately 10:30 AM. The laboratory performs approximately 6000 hematology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Monthly Quality Assurance Overview, review of the Monthly Checkoff List, review of the PTevaluations and corrective actions, review of the Dimension Xpand Daily Maintenance log, review of the Wright Giemsa QC log, and review of the Corrected Report Investigation form revealed that the laboratory director failed to ensure that the established quality assessment program was maintained to assure the quality of the laboratory services provided. Findings include: The established QA program was not maintained to fully communicate and provide documentation to the laboratory director regarding the status of the laboratory. 1. The

	Monthly Quality Assurance Overview forms reviewed for July, August and September 2017 did not document the 60% score for the unacceptable performance for eosinophils from the second PT event of 2017. The PT evaluation was printed from the API website on 8/17/17 but the PT Corrective Action and PT Evaluation forms were not completed until 11/06/17. A review of the Corrective Action form for the unacceptable performance for eosinophils for the second event of 2017 completed on 11/06/17 revealed that there was no evaluation of whether patient results were affected from 7/12/17 to 11/07/17 when the ACT 5 Diff hematology analyzer was recalibrated. This corrective action form was not signed by the laboratory director. There was no documentation until 11/01/17 that the laboratory director was informed about the unacceptable performance for eosinophils from the second hematology PT event of 2017 tested in July 2017. 2. The Monthly Quality Assurance Overview form reviewed for July, August and September 2017 indicated that all maintenance was completed and the Monthly Checkoff List indicated that maintenance reports were checked for the Dimension Xpand chemistry analyzer. A review of the Daily Maintenance log for the Dimension Xpand revealed cuvette temperature records exceeded the manufacturer's established limit for 21 days from July through September 2017. Corrective action was not taken until 10/31/17 when the log noted that the cuvette temperature was recalibrated. 3. The Monthly Checkoff List for January 2018 did not note the expiration date of 1/12/18 for solution 3 used in the Wright Giemsa stain used to stain patient blood smears for manual review. The Wright Giemsa QC Log noted that the expiration date for solution 3 as 1/12/18; however, there were QC records on the form from 1/19/18 to 2/02/18. A new QC log was started on 2/05/18 with the same 1/12/18 expiration date for solution 3 written on the form. 4. The Monthly QA Overview and the Quarterly QA Review reported "no issues" for the Xpand chemistry analyzer. There was no documentation that the glucose reference range had been changed in May 2017 and there were corrected reports issued for patient glucose test results from 5/01/17 to 7/17/17. The laboratory performs approximately 26,560 chemistry and 6,000 hematology tests annually.