

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1044203	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Cash Clinical Of Carson City	Street Address, City, State 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 2/11/2020. 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.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview with laboratory personnel, the laboratory failed to retain the quality control records for the Beckman Coulter ACT 5 Diff, hematology analyzer, for January 2019. Findings include: 1. Review of quality control results for the ACT 5 Diff, hematology analyzer, for January and February 2019, revealed that the laboratory did not retain the QC records for January 2019. 2. Laboratory personnel #1 interviewed during the on-site inspection on 2/11/2020 at approximately 4:00 PM could not locate the printed QC records and could not retrieve the QC records on the hematology analyzer. The laboratory performs approximately 6,300 hematology tests annually.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the ACT 5 Diff CP Maintenance Check List, Dimension Expand Daily, Weekly/Monthly Maintenance logs, and the Dimension Xpand Quiklyte Results, and interview with laboratory personnel, the laboratory failed to ensure equipment maintenance was performed as required. Findings include: 1. Review of the ACT 5 Diff CP Maintenance Check List for January-February 2019 revealed that there were no daily maintenance records on January 21, 22, 28, and 29 and February 4, 5, 6, 18, 20, and 26, 2019 for the hematology analyzer. 2. Review of the Dimension Expand Daily and Weekly/Monthly Maintenance logs from March to July 2019 revealed that: a. there were no daily maintenance records on June 20, 21, 25, 26, 27, 28 and July 1, 3, 5, 17, 25, 26, and 31, 2019; b. there were no weekly maintenance records on 3/25-29, 4/01-05, 4/22-26, 4/29-5/03, 6/17-28, 7/01-05, and 7/22-26/2019; and c. there were no monthly maintenance records for June and July 2019 for the chemistry analyzer. 3. Review of the Dimension Xpand Quiklyte Results from 7/07 /2019 to 1/27/2020 revealed that no dilution check was documented on 9/19/2019. Laboratory personnel #1 interviewed during the on-site survey on 2/11/2020 at approximately 3:45 PM confirmed the findings. The laboratory performs approximately 6,300 hematology and 28,020 chemistry tests annually.

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 review of corrected patient reports, review of Siemens Dimension Expand chemistry analyzer result printouts, and interview with laboratory personnel #1, 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. Review of corrected patient reports from 4/02/2018 to 4/04/2018 and the Dimension Expand instrument printouts revealed that four of four reports contained chemistry test results on the final patient report that did not match the results on the instrument printouts. a. Accession #34045 tested on 4/02/2018 on the Dimension Expand reported a glucose result of 86 on the instrument printout and the patient report had a result of 66 mg/dL. b. Accession #34055 tested on 4/02/2018 on the Dimension Expand reported a glucose result of 86 on the instrument printout and the patient report had a result of 46 mg/dL. c. Accession #34064 tested on 4/02/2018 on the Dimension Expand reported a Calcium result of 9.3 and a Creatinine of 1.11 on the instrument printout and the patient report had a Calcium result of 9.0 and a Creatinine of 3.00 mg/dL. d. Accession #34092 tested on 4/04/2018 on the Dimension Expand reported a Triglyceride result of 59 on the instrument printout and the patient report had a result of 49 mg/dL. 2. Laboratory personnel #1 interviewed during the on-site survey on 2/11

/2020 at approximately 5:00 PM stated that the Dimension Expand is interfaced with the LabDaq laboratory information system (LIS) for the test results to transfer directly to the patient reports. She was unable to explain the discrepancies in the test results from the instrument print out with the patient reports. The laboratory performs approximately 28,020 chemistry 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 corrected patient reports, review of Siemens Dimension Expand chemistry analyzer result printouts, and interview with laboratory personnel #1, the laboratory failed to ensure that corrected reports are issued promptly to the authorized person ordering the test. Findings include: 1. Review of corrected patient reports from samples reported on 4/03/2018 to 4/05/2018 and the Dimension Expand instrument printouts revealed that four of four patient reports did not contain the corrected results. a. The corrected report packet for #34045 did not contain a corrected report for that accession number. The comment, "Corrective results for glucose reported on 4/19/18. FJC PT notified via post card 4/19/18 LSC," was added to accession #34179 instead of accession #34045 which contained the incorrect glucose result. Both accession numbers are from the Sample Patient ID #23658 but collected on different days. #34045 was collected on 3/31/18 and #34179 collected on 4/12/2018 . b. The original patient report for accession #34055 from 4/03/2018 reported a glucose of 46 mg/dL. The corrected report issued on 4/19/2018 reported the same result instead of 86 mg/dL which is on the instrument printout. c. The original patient report for accession #34064 from 4/05/2018 reported a calcium of 9.0 and a creatinine of 3.00 mg/dL. The corrected report issued on 4/19/2018 reported the same calcium and creatinine results instead of 9.3 and 1.11, respectively, which are on the instrument printout. d. The original patient report for accession #34092 from 4/05/2018 reported triglycerides of 49.0 mg/dL. The corrected report issued on 4/19/2018 reported the same result instead of 59 mg/dL which is on the instrument printout. 2. Laboratory personnel #1 interviewed during the on-site inspection on 2/11/2020 at approximately 5:00 PM confirmed that the corrected reports did not contain the correct results for the tests reported in error. The laboratory performs approximately 28,020 chemistry tests annually.

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 corrected patient reports, equipment maintenance records, review of equipment service records, and the quarterly quality assurance review for the first quarter of 2019, the laboratory director failed to ensure that the established quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings include: 1. The QA program failed to identify and provide documented corrective actions for the quality issues in the analytic and post-analytic phases of testing discovered during the on-site survey on 2/11/2020. 2. Review of the corrected patient reports from April 2018 revealed that: a. the reported test results did not match the instrument printout test results from the Dimension Xpand; b. the corrected reports did not contain the correct test results; and c. the patient reports documented the initials of the testing personnel belonging to laboratory personnel with no training and competency evaluations for tests performed on the chemistry and hematology analyzers. d. There was no documented investigation and resolution of these findings. 3. Review of the equipment daily, weekly and monthly maintenance records revealed that the required maintenance was not performed and documented as required for the chemistry and hematology analyzers. There were no corrective actions taken and documented for the required equipment maintenance activities. 4. The first quarter QA review for 2019 recorded "no issues" for the Beckman ACT 5 Diff hematology analyzer although the QC review showed that QC records were not retained for January 2019, the maintenance log review showed 10 days from January through February when daily maintenance was not performed and documented, and the Beckman Coulter service report indicated that service was performed by the manufacturer for a problem call on 1/23/2019.

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 review patient test reports, review of Form CMS-209, review of testing personnel competency documentation, and interview with the laboratory personnel #2, the laboratory director failed to ensure that all testing personnel were evaluated for competency to perform test procedures and report test result promptly, accurately, and proficiently. Findings include: 1. Review of four corrected patient test reports from April 2018 revealed reports containing the initials of testing personnel not listed on CMS Form-209. a. The report for accession #34064 stated, "Run by LSC on 4/2/2018 1:35 PM," for the Complete Blood Count (CBC), Differential, and Absolute Cell Count. b. The report for accession #34045 stated, "Run by LSC on 4/3/2018 7:07 AM," for the Comprehensive Metabolic Panel. c. The report for accession #34055 stated, "Run by LSC on 4/3/2018 12::35 PM," for the CBC, Differential, and Absolute Cell Count. d. The report for accession #34092 stated, "Run by LSC on 4/4/2018 2:09

PM," for the Lipid Panel. 2. There were no competency assessments for testing personnel with the initials, LSC, to perform moderate complexity chemistry and hematology tests. 3. Laboratory personnel #2 interviewed during the on-site survey on 2/11/2020 at approximately 4:30 PM stated that the initials, LSC, were hers. She confirmed that as a laboratory assistant, she does not run tests on the chemistry or hematology analyzers and could not explain why her initials were on the patient reports as the testing personnel. The laboratory performs approximately 28,020 chemistry and 6300 hematology tests annually.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on review of Form CMS-209 and the Division of Public and Behavioral Health (DPBH) records, one of two the technical consultants did not possess a current license issued by the State of Nevada. Findings include: Review of Form CMS-209 revealed two personnel designated as a technical consultant. Review of DPBH records revealed that one of two technical consultants did not possess a current license. The Licensed Laboratory Director's license expired on 3/31/2015.