

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 29D1044203	<b>(X3) Date Survey Completed</b> 04/26/2022
<b>Name of Provider or Supplier</b> Cash Clinical Of Carson City	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 4/26/2022. 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.
<b>D5303</b>	<p>TEST REQUEST CFR(s): 493.1241(b)</p> <p>The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, "Ordering of Tests," review of the laboratory requisition forms randomly selected from May 2020 through March 2022 included in the monthly quality assessment internal audit, and interview with the laboratory assistant on duty on the day of the survey, the laboratory failed to obtain a written or electronic request for tests ordered verbally on 8/09/2020 for patient with initials, SG, Date of Birth 3/19/1980. Findings include: 1. Laboratory procedure, "Ordering of Tests," states, "c. The name of the person who called the verbal order is documented on the Laboratory Request Form. d. The physician/physician's office must send a fax with the verbal order and the fax must be signed." 2. The laboratory requisition form dated 8/9/20, reviewed for patient with initials, SG, Date of Birth 3/19/1980, noted that the doctor called to add on Complete Blood Count, Lipid, urinalysis, and uric acid. The laboratory was unable to locate during the on-site survey, the faxed, written or electronic request for the tests added on verbally. 3. The laboratory assistant on duty interviewed during the on-site survey on 4/26/2022 at approximately 1:30 PM was not clear on what steps to take for verbal orders, confirmed that the faxed order</p>

was not filed together with the original requisition form, and indicated that the faxed requisition may be stored in an off-site location. The laboratory performs approximately 29,500 chemistry and 7,000 hematology 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 review of laboratory procedure, "Validation Testing (Parallel Testing) Correlation between Instruments or Methods," review of verification studies performed for new test, hemoglobin A1c, on the Dimension Expand, and interview with the laboratory manager, the laboratory personnel failed to follow the director approved, written procedure. Findings include: 1. Laboratory procedure, "Validation Testing (Parallel Testing) Correlation between Instruments or Methods," states, "If a new test is done in house, at least 10 patient samples will be run in house and will also be sent to a reference laboratory and a statistical comparison of the results obtained in house and at the reference laboratory will be done. . . No analyte result on patient sample will be released by Cash Clinical until validation has been satisfactorily completed." 2. Method validation records for hemoglobin A1c on the Dimension Expand performed in December 2020 did not have correlation studies performed for ten patient samples tested in house and at a reference laboratory. 3. The laboratory manager interviewed during the on-site survey on 4/2/2022 at approximately 2:00 PM confirmed the findings. The laboratory performs approximately 29,500 chemistry tests annually.

**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 review of laboratory personnel records and interview with the laboratory manager, the technical consultant failed to ensure that competency evaluations were conducted annually for testing personnel performing moderate complexity testing after the first year. Findings include: 1. Review of laboratory personnel records revealed that one of two testing personnel employed for more than one year performing moderate complexity testing did not have competency evaluations performed in 2020 and 2021. 2. The laboratory manager interviewed during the on-site survey on 4/26/2022 at approximately 2:30 PM indicated that the documentation could not be located. The laboratory performs approximately 29,500 chemistry and 7,000 hematology tests annually.