

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2246185	(X3) Date Survey Completed 07/18/2023
Name of Provider or Supplier Lutheran Hospital - Cance Centers Of Co	Street Address, City, State 400 Indiana St, Ste 310, Golden, CO	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant (TC), the laboratory failed to perform competency for the position of TC for one out of one TC listed on the CMS-209 and failed to perform competency assessment for two out of two testing personnel for testing performed on the Abbott I-Stat Chem 8 since April 2022. Findings include: 1. A review of personnel records revealed the laboratory failed to perform competency assessment for the position of technical consultant on one out of one TC listed on the CMS-209. 2. A review of personnel records revealed the TC had competency documentation that was performed at another laboratory on 4/12/2022. 3. A review of personnel records revealed the laboratory failed perform competency assessment on two out or two testing personnel for tests performed on the Abbott I-Stat Chem8 since April 2022. 4. An interview on 07/18/2023, at approximately 5:10 PM, confirmed the laboratory failed to perform competency for the position of TC at the laboratory.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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)</p>

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 a record review and an interview with the technical consultant, the laboratory failed to ensure that the Abbott I-Stat Chem8 was verified for performance prior to the start of patient testing in April 2022. The laboratory performed approximately 182 patient samples annually. Findings include: 1. A review of the laboratory documents for the Abbott I-Stat Chem8 cartridge revealed the laboratory failed to verify the performance specifications for accuracy, precision, and reportable range since the start of testing in April 2022. 2. An interview on 07/18/2023, at approximately 4:00 PM, confirmed the laboratory failed to verify the performance of the Chem 8 cartridge.

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 record review and an interview with the laboratory technical consultant, the laboratory failed to ensure that the correct laboratory location that performed tests on the Abbott I-Stat Chem 8 and reported patient results was stated on the report form since April 20202. The laboratory performed approximately 182 samples on the Abbott I-Stat Chem8. 1. A review of the laboratory patient test reports revealed that the patient Chem8 results were performed at another laboratory since April 2022. 2. An interview with the technical consultant on 7/18/2023, at approximately 5:20 PM, confirmed that the patient test reports for the Chem8 tests were failed to state the correct laboratory which performed the test.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the technical consultant (TC), the TC failed to ensure that competency assessment was performed on two out of two testing personnel at least semi-annually the first year of patient testing on the hematology Sysmex XN since April 2022. Findings include: 1. A review of laboratory records revealed the TC failed to perform competency assessments at least semi-annually in the first year of patient testing for two out of two testing personnel who test and report

patient specimens in the specialty of hematology. 2. The laboratory performed approximately 10,000 patient specimens annually. 3. An interview with the TC on 7/18/2023, at approximately 3:30 PM, confirmed that semi-annual competency was not performed on testing personnel the first year of patient testing.