

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1053125	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier Intermountain Cedar City Instacare	Street Address, City, State 962 Sage Dr, Cedar City, UT	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to enroll in proficiency testing for the sub-specialty of routine chemistry for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, and Blood Urea Nitrogen, Creatinine and Calcium tests performed on the iSTAT instrument using Chem 8+ cartridges. The laboratory performed approximately 1-3 tests per month. Findings include: 1. The laboratory failed to enroll in proficiency testing for Chem 8+ test cartridge tests performed on patient 541820968 on 01/29 /2020. 2. In an interview with staff on 02/05/2020 at approximately 11:40 A.M. staff confirmed they had not enrolled in an approved proficiency program for Chem 8+ cartridges in 2020.</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</p>

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 cartridge package information observed, patient test record review, lack of documentation, and laboratory staff interview the laboratory failed to establish performance specifications for iSTAT Chem 8+ test cartridges in use on 01/29/2020 for 1 of 1 patient tested (#541820968) since Food and Drug Administration's (FDA) withdrawal of Chem 8+ cartridges approval as a waived test (January 15 2020) and subsequent reclassification as a moderate complexity test on 02/19/2020. Findings include: 1. Based on cartridge package identification for the Chem 8+ on 02/05/2020 at approximately 11:30 A.M. and quality control records review for Chem 8+ cartridge performed on 01/21/2020 the laboratory used Chem 8+ cartridges to report sodium, potassium, chloride, carbon dioxide, blood urea nitrogen, glucose, creatinine, and calcium testing on the iSTAT instrument. 2. Patient test record review for patient 541820968 included documentation the laboratory used Chem 8+ cartridge lot number 00010710 on 01/29/2020. 3. The laboratory failed to document precision, and reportable range studies for Chem 8+ cartridges prior to testing patient 541820968. 4. In an interview conducted on 02/05/2020 at approximately 11:40 A.M. the technical consultant stated the laboratory did not perform a verification study to verify the precision and reportable range verification for the cartridges in use on 02/05/2020 and prior to patient testing performed on 01/29/2020.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with staff, the laboratory failed to perform two levels of quality control each day of Chem 8+ test cartridge testing for 1 of 1 patient tested since reclassification of Chem 8+ blue cartridges from waived to moderate complexity tests. The laboratory performed approximately 1 to 3 tests per month. Findings include: 1. The laboratory performed testing on 01/29/2020 for patient 541820968. 2. The laboratory did not document two levels of quality control performance on 01/29/2020. 3. In an interview conducted on 02/05/2020 at approximately 11:40 A.M. staff confirmed they did not perform quality control each date of Chem 8+ testing.

D6055

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 whenever test methodology or instrumentation changes. The individual's performance must be

reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on lack of training documentation and interview with staff, the technical consultant failed to ensure testing personnel received training and competency evaluation for the use of Chem 8+ test cartridges as moderate complexity tests for Sodium, Potassium, Chloride, Carbon Dioxide, Blood Urea Nitrogen, Glucose, Creatinine and ionized Calcium prior to performing patient testing on 01/209/2020 for patient 541820968. The laboratory performed approximately 1-3 tests per month. Findings include: 1. The laboratory failed to document testing personnel received training and competency evaluations following the change of test categorization for iSTAT chemistry testing on the Chem 8+ cartridge from waived to moderate complexity requirements before reporting test results patient 541820968 on 01/29/2020. 2. On 02/05/2020 at approximately 11:10 A.M. staff, confirmed they had not performed training and performance evaluations for moderate complexity testing personnel when the test categorization changed to ensure testing personnel were updated on specimen collecting, testing, and reporting of moderate complexity tests.