

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2152101	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier Intermountain Lehi Instacare	Street Address, City, State 3249 North 1200 West Ste A, Lehi, 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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation, and confirmation by staff, the laboratory failed to verify 1 of 1 high complexity test system test performed from January 15, 2020 to February 19, 2020 for approximately 160 Chem 8+ tests (Sodium, Potassium, Chloride, Carbon Dioxide, glucose, Urea Nitrogen, Hematocrit, and ionized Calcium) performed for an unapproved Food and Drug Administration (FDA) Abbott iSTAT Chem 8+ test cartridge prior to reporting patient test results. The laboratory performed approximately 10 Chem 8+ tests per week. Findings include: 1. Patient test records review included documentation the laboratory used iSTAT Chem 8 test cartridges between January 15, 2020 and February 19, 2020 when the FDA withdrew waived test categorization for the test system. . 2. The laboratory lacked documentation they verified the accuracy, precision, reportable range, analytical sensitivity and specificity prior to testing patient samples after the FDA waived test categorization was withdrawn. Tests that are not categorized by FDA default to high complexity testing. (FDA granted moderate complexity categorization February 19, 2020). 3. The laboratory failed to document establishment of the normal</p>

range for Chem 8+ tests on the moderately complex iSTAT cartridges. 4. In an interview conducted on 01/13/2020 at approximately 6:00 P.M. staff confirmed the lab continued to use the Chem 8 + Blue cartridges without verification of the test specifications for tests that were not FDA approved each day of testing between January 15, 2020 and February 19, 2020 and did not verify the accuracy, precision and reportable range for Chem 8+ tests until March 05,2020 for the then recategorized moderately complex test.