Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2080583	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Intermountain Draper Instacare	**Street Address, City, State** 12473 South Minuteman Drive, Draper, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual approval review, instrument verification records review, patient test records review and interview with staff, the laboratory director failed to sign and date 2 of 2 new procedures as approved prior to the laboratory performing testing for the iSTAT Chem 8+ test system and Complete Blood Count (CBC) tests. The laboratory performed approximately 1 test per day. Findings include: 1. The laboratory procedure manual was approved for iSTAT Chem 8 + test and CBC tests performed on the XN430 instrument on 09/10/2020. 2. Patient test record review included documentation the laboratory reported XN430 test results on 02/20/2020 for patient 543941909 and reported iSTAT Chem 8+ test results on 04/10/2020 for patient 645355955. 3. Instrument verification records review included test specification verification dates of 02/26/2020 for the XN430 and on 03/19/2020. 4. In an interview with staff on 09/16/2020 at approximately 6:00 P.M. staff confirmed the director failed to approve the procedures prior to testing patient specimens.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to monitor the test conditions for Sysmex XN 430 complete blood count (CBC) analyzer Humidity percent for approximately 6 months of testing from March 2020 to September 16, 2020. The laboratory performs approximately 1 CBC tests per day. Findings include: 1. The laboratory lacked documentation they monitored the percent humidity as specified by the XN430 to be at least 10%, 2. In an interview conducted on 09/16/2020 at approximately 4:40 P.M. staff confirmed the laboratory did not record percent humidity for testing and reporting CBCs.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) 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. This STANDARD is not met as evidenced by: Based on 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 30 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. Findings include: 1. 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). 2. In an interview conducted on 09/16/2020 at approximately 5:45 P.M. the laboratory technical consultant stated 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 and 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.
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 patient test records review, lack of documentation, and interview with staff, the laboratory failed to document two levels of control performance each day of testing for iSTAT chem 8 tests performed on 04/10/2020. Findings include: 1. Patient test record review for testing performed for 64555955 on 04/10/2020 included documentation the laboratory reported iSTAT Chem 8+ testing. reported Sodium of 140 mg/dl, Potassium 3.4 mg/dl, Chloride of 105, and BUN of 11 mg/dl. 2. The laboratory lacked documentation of quality control performance for testing performed on 04/10/2020. 3. In an interview conducted on 09/16/2020 at approximately 5:30, staff confirmed QC was not documented for testing performed on 04/10/2020.
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 competency evaluation records review, patient test records review, lack of documentation, and interview with staff, the technical consultant failed to evaluate 1 of 8 testing personnel annually in 2019 for complete blood cell testing. Findings include: 1. Competency test records review failed to include competency records for test person "I". 2. Patient test records review included documentation test person "I" performed testing on 12/12/2018
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on direct observation on 09/16/2020, procedure manual review, and confirmation by staff, testing personnel failed to follow the laboratory's procedure for handling iSTAT Chem 8+ test cartridges for 1 of 1 patient's test observed. Findings include/ 1. Direct observation on 09/16/2020 at approximately 5:05 P.M. included noting staff opened the room temperature foil pouch containing the iSTAT Chem 8+ test cartridge. The test was not performed until 5:25 after the specimen was collected. 2. Procedure manual review included the instruction to open the foil pouch containing the iSTAT cartridge immediately prior to applying the patient specimen. 3. In an interview conducted on 09/16/2020 at approximately 6:00 P.M., staff confirmed testing personnel failed to open the test cartridge pouch immediately prior to performing the tests.