Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2143596	01/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Intermountain Orem Imaging Center	458 W 800 N, Orem, 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
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 procedure review, temperature and test records review, and interview with staff, the laboratory failed to record Creatinine and prothrombin time storage and testing temperatures each day of testing for 2 of 10 test days reviewed. The laboratory performed approximately 25 tests per year. Findings include: 1. Procedure review for prothrombin time and Creatinine testing included documentation that cartridge storage was to be monitored and recorded daily to ensure the storage temperature was between 2 and 8 degrees C and testing temperature was between 20 and 25 degrees C. 2. The laboratory failed to record cartridge storage and testing temperatures on 11/18 /2019 and 10/25/2019. 3. Patient test records review included documentation patients 1226842372 was tested on 11/18/2019 for prothrombin time and patient M1418177 was tested on 10/25/2019 for Creatinine testing. 4. In an interview with staff on 01/10 /2020 at approximately 4:45 P.M., staff confirmed the temperatures were not recorded on 11/18/2019 or 10/25/2019 and patients were tested.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Individualized Quality Control Plan (IQCP) review, lack of documentation, and interview with the technical consultant, the laboratory IQCP failed to include a quality assurance plan stating the frequency the director would review the plan for its effectiveness to identify test problems for Creatinine and Prothrombin time tests. The laboratory performed approximately 25 Prothrombin time and creatinine tests per year. The laboratory director had not reviewed the IQCP since December 19, 2018. Findings include: 1. The IQCP for iStat creatinine and Prothrombin time tests failed to include a quality assessment plan stating the frequency the director would review the reagent quality control, environmental compliance, specimen collection process compliance, test system monitors, and testing personnel competency. 2. In an interview with the technical consultant on 01/10/2020 at approximately 4:30 P.M. the technical consultant confirmed the director had not reviewed the IQCP in 2019 to ensure reducing the quality control performance to monthly and with each new lot number of reagent cartridges provided sufficient information to ensure the tests were performed accurately and reliably.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on test and quality control records review and confirmation by the technical consultant, the laboratory failed to perform quality control prior to testing patients when a new lot number of Creatinine test cartridges was started. The laboratory tested approximately 1 to 2 Creatinine tests per month. Findings include: 1. Test records review included documentation the laboratory performed Creatinine tests using lot number A18214 iSTAT cartridge for patient 1218948468 on 12/272018. 2. Quality control records review failed to include records that quality control was performed for lot number A18214 prior to testing the patient on 12/27/2018. 3. In an interview with the laboratory technical consultant on 01/10/2020 at approximately 4:15 P.M., staff confirmed quality control was performed on 12/28/2018 after testing the patient on 12/27/2018.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i)

	The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on i STAT prothrombin time procedure review and interview with staff, the technical consultant failed to include direct observation of specimen collection using capillary tubes for prothrombin time testing for the evaluations performed September of 2018 and June of 2019. The laboratory performed approximately 25 creatinine and prothrombin time tests per year. Findings include: 1. Prothrombin time procedure states specimens are to be collected by direct fingerstick (capillary) puncture onto the cartridge or by venipuncture using plastic syringe. 2. In an interview with testing personnel on 01/10/2020 at approximately 3:45 P.M. staff stated testing personnel used capillary tubes for specimen collection (the only capillary tubes present on 01/20 /2020 were heparin coated glass tubes). 3. In an interview with the technical consultant on 01/10/2020 at approximately 4:30 P.M., the technical consultant confirmed the competency evaluation failed to include direct observation of specimen collection using capillary tubes for prothrombin time testing.