Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2143596	07/17/2018
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with staff, the Istat procedure manual failed to include the requirement for specimen collection and acceptability for 1 of 1 test system in use (Istat). The laboratory started Istat testing in 03/2018 and had performed approximately 25 tests. Finding include: 1. The Istat procedure manual did not contain instructions for sample collection and handling for Prothrombin Time/INR and Creatinine testing. 2. The technical consultant stated on 07/17/2018 at approximately 11:00 a.m., the Istat procedure was a corporate policy and had not been adapted to reflect unique protocols for testing at the imaging center.

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 and interview with staff, the IQCP plan failed to include laboratory acquired data to support the laboratories quality control (QC) plan to reduce the frequency of external QC to each new cartridge lot and shipment and failed to specify what constitutes suitable reference material for "new reagent confirmation of acceptability" for 1 of 1 IQCPs reviewed. (Istat). Findings include: 1. No laboratory generated data was included with the IQCP to support the laboratory's Quality Control Plan to reduce the frequency of external quality control from the each day of testing (for non-waived Creatinine specimens) or every 8 hours (for Prothrombin Time/INR testing) on the Istat to with each new lot or shipment of test cartridges. 2. The laboratory's IQCP states to confirm the acceptability of new reagent lot numbers and shipments using suitable reference material before or concurrently with being placed in service, but failed to define the number or type of controls/reference materials to use. 3. The technical consultant stated on 07/17/2018 at approximately 12:00 p.m. the IQCP was based on a corporate plan and the laboratory did evaluate laboratory specific data to determine if the plan was appropriate for their testing location.
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 patient test report review and interview with staff, the test report lacked the name and address of the laboratory location where the test was performed on 3 of 3 patient test reports reviewed. Findings include: 1. The Prothrombin Time test report for patient 1214576187 tested on 05/30/2018 and Creatinine test reports for patient 1213539460 tested on 04/13/2018 and patient 1215207540 tested on 06/22/2018 list the testing location as Intermountain Laboratories-Orem Community Hospital, 331

	North 400 West, Orem, Ut 84057. 2. Staff confirmed during survey on 07/17/2018, testing had been performed onsite at Orem Imaging Center 458 West 800 North, Orem, Ut 84057.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to ensure a quality assessment program was established to assure the quality of laboratory services provided for 2 of 2 non-waived tests performed (Prothrombin Time/INR and Creatinine). The laboratory began testing in 03 /2018 and had performed approximately 25 tests. Findings include: 1. The procedure manual failed to include a written quality assessment program for Prothrombin Time /INR and Creatinine testing. 2. Staff stated on 07/17/2018 at approximately 12:00 a.m. the laboratory lacked documentation of quality assessment activities that monitored the quality of laboratory services throughout the pre-analytical, analytical, and post-analytical phases of testing.