Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409549	04/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Intermountain Health,	1315 Golden Valley Circle, Billings, MT	

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
D0000	A validation survey was performed on April 29,2026, with the following standard level deficiencies cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Speed and Time Microscopic Urines: Based on review of the laboratory's urinalysis procedure, direct observation,centifuge manual, and interview with Technical Consultant #2 , the laboratory failed to address in their procedure centrifuge time and speed when performing microscopic urines in the last two months as evidenced by: 1.

	In review of the laboratory's procedure titled, "HEPKS5214 Urinalysis Manual Microscopic" version 1.3, the laboratory did not address centifuge speed and time within the procedure. 2. In direct observation at 0959 Xtrafuse Ultra Centifuge LW scientific, the laboratory was centrifuging urine specimens at 3200 revolutions per minute (RPMS) at 10 minutes. 3. In review of the Xtrafuse Ultra Centifuge LW scientific manual stated in a chart, "whole blood speed 3300 RPMS 10 min... urine 1800 RPMs 5 mins." 4. In interview with the Technical Consultant #2 at 0959, she confirmed that they were spinning down the specimens at 3300 RPMS for 10 minutes and they did not have speed and time addressed. 5. The laboratory performed 91 microscopic urines from April 1, 2025 to December 31,2025. References for Microscopic Urines: Based on review of the laboratory's policy and procedures, and interview with Quality Assurance manager, the laboratory failed to have references in their procedure for performing microscopic urines for the last two months as evidenced by: 1. In review of the laboratory's procedure titled, "HEPKS5214 Urinalysis Manual Microscopic" version 1.3, the laboratory did not have any references related to performing microscopic urines. This included not address centrifugation speed or time, specimen preparation or storage. 2. In an interview at 1005, with the Quality Assurance manager confirmed that the urine microscopic procedure did not have any references. 3. The laboratory performed 91 microscopic urines from April 1, 2025 to December 31,2025.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual for chemistry, corrective action /problems log, chemistry Quality control (QC) records, and confirmed in interview with Technical consultant #2, the laboratory failed to follow their own policy to evaluate patient test results after performing test system adjustments for QC failures since the last acceptable QC run to determine if test results were affected for 115 of 115 patients (AST, ALT) from testing event 1/12/2026 to 1/13/2026 as evidenced by: 1. In review of the laboratory's procedure QA0010 Quality Control Program version 17.0 under Re-evaluation of Reported Patient Results (Patient Lookback), stated. "Reevaluate results when: Calibration, replacement of reagents, maintenance/service, replacing or adjusing insturment components or other corrective action must be performed to bring an analytic system back into control. Re-evaluation is not required if only QC material was the issue or no patient were run since the last acceptable QC. " 2. In review of the Chemistry Quality Control records for ALT and AST the laboratory, the following QC failed. a. ALT range 93-109 U/L (Quality control result was 90 U/L) which triggered a 2-2S rule failure on 1/13/2026 b. AST range 199-222 U /L (Quality control result was 193 U/L) which tiggered a 2-2S rule failure on 1/13 /2026. 3. In review of the laboratory's corrective action log Titled, "Quality Control /Instrument Problems log on 1/13/2026 stated, "ALT & AST QC out of range 2 flush pimp errors, greased flush pump, replaced R2 prob tip, cleaned drains, changed source lamp, man offset after 30 mins." The laboratory did have any documentation to show

	they had evaluated patients as per their procedure. 4. In interview with Tehnical consultant #2 at 1302, she confirmed that they did not go back at evaluate patient since the last acceptable Quality control. 5. The laboratory performed 115 (ALT, AST) specimens from 1/12/2026 (last successful QC) to 1/13/2026 (failed QC).