Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2121595	12/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mountain View Hospital Pathology	2325 Coronado St, Idaho Falls, ID	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation and interview with testing personnel 1, the laboratory failed to establish written policies and procedures to ensure the quality of the laboratory services provided. The findings include: 1. QA policies and procedures for the general lab system (GLS) were not presented for review during the survey, including but not limited to, policies and procedures specific to biannual verification testing, personnel competency, instrument maintenance and corrective actions. See D5429, D5781 2. An interview with testing personnel 1 on 12/01/2020 at 1:00 pm, confirmed that there were no QA policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the general laboratory systems. 3. The laboratory reports performing 90 frozen sections annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct observation and an interview with the laboratory manager on 12/01 /2020, the laboratory failed to label the Haemotoxylin and Eosin (H&E) stains and reagents used in the H&E staining system with the lot numbers and expiration date. The findings include: 1. Direct observation of the H&E staining system containers, during a laboratory tour with the laboratory manager, revealed that the stains and reagents were not labeled with the lot numbers and expiration dates from the original containers. 2. Laboratory procedure states all reagents must not be used after expiration. 3. An interview with the laboratory manager on 12/01/2020 at 10:30 am, confirmed that the laboratory failed to label the H&E staining system containers with the lot numbers or expiration dates after pouring stains and reagents from the original containers. 4. The laboratory reports performing 90 frozen sections annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager on 12/01/2020, the laboratory failed to perform maintenance as defined by the manufacturer and with at least the minimum specified frequency. The findings include: 1. The Leica cryostat manual states that the instrument must be have the plastic coupling oiled and the specimen cylinder lubricated weekly. The clamping piece on the microtome, the clamping lever and the slot cover need to be oiled. The air inlet opening needs cleaned when there is visible pollution. 2. A record review of the laboratory logs revealed that the laboratory failed to document weekly or other maintenance required by the manufacturer on the Leica cryostat since the last inspection on 6/28/2018. 3. An interview with testing personnel 1 on 12/01/2020 at 1:30 pm confirmed that the laboratory had not performed weekly or other required maintenance on the Leica cryostat since the last inspection on 6/28/2018. 4. The laboratory reports performing 90 frozen sections annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review of cryostat temperature logs for 2019 and 2020, the Leica

	cryostat manual and an interview with the laboratory manager on 12/01/2020, the laboratory failed to document corrective actions taken when the cryostat was performing outside of the established operating temperature parameters. The findings include: 1. A record random review of the Leica cryostat temperature log for 2019 with an established temperature range of -18C to -25C, based on laboratory procedure, revealed that three days out of 30 days had temperatures documented above the established range. 2. There were no documented corrective actions for the three days in which the temperatures for the Leica cryostat were documented out of the established range, -18C to -25C. 3. An interview with the laboratory manager on 12/01 /2020 at 9:30 am, confirmed that there were no documented corrective actions for the out of range temperatures in the Leica cryostat temperature log for 2019 . 4. The laboratory reports performing 90 frozen sections annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record reviews of procedures and polices, training and competency records, maintenance and temperature logs and interviews with the laboratory manager and testing personnel 1 on 12/1/2020, the technical supervisor failed to fulfill his responsibilities for evaluating the capabilities of the testing personnel and assuring that each individual performing tests receives regular in-service training and education appropriate for their responsibilities. The findings include: 1. A record review of maintenance and temperature logs revealed that the technical supervisor failed to identifying training needs and assure that each individual performing tests receives regular in-service training and appropriate education to ensure performance of their responsibilities. See D5429, D5781. 2. A record review of the CMS 209 personnel form and training and competency records revealed that the technical supervisor failed to ensure that the testing personnel were competent to perform test procedures. One (1) of four (4) testing personnel with a hire date of 7/2020 did not have documentation of initial training and three (3) of four (4) testing personnel did not have documentation of annual competency for 2018, 2019 and 2020. 3. An interview with the laboratory manager and testing personnel 1 confirmed that there were no documented training and competency for 4 out of 4 testing personnel. 4. The laboratory reports performing 90 frozen sections annually.