Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2151225	08/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Red Mountain Diagnostics	140 Oxmoor Blvd Suite 140, Homewood, AL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on reviews of the Accuracy Comparison documentation, the procedure entitled, "Quality Management Program", and an interview with the Laboratory Director, the laboratory failed to ensure an assessment and comparison of the consulting laboratory's Histopathology results and the laboratory's results was documented. This was noted from the previous survey (03/23/2022) to the current survey (08/29/2023). This is a repeat deficiency. The findings include: 1. A review of the laboratory menu revealed the laboratory performed Histopathology reading and interpretation on-site for patients. In some cases patients then went to the University of Alabama in Birmingham (UAB) for a second opinion. UAB requested the patient's slides from Red Mountain Diagnostics (RMD) and performed a completely new Histopathology assessment. The UAB findings were returned RMD, and utilized as accuracy verification for the specialty of Histopathology. However, upon review of the accuracy verification records, there was no documentation of the laboratory's review (signature and date) and comparison of the results from the two laboratory's. There was no indication of an assessment with documentation of corrective actions for any discrepancies. 2. A review of the procedure entitled, "Quality Management Program" on page 6 revealed "...C. Pathology Peer Review" ... "... a review of quality by the Pathologist Peer Review process (10% review)". 3. During an interview on August 29, 2023, at 3:00 PM, the Laboratory Director confirmed the accuracy verification reviews were not documented after the UAB results were returned. .
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 a review of the environmental records, the TissueTek VIP Processor operating conditions, and an interview with the Laboratory Manager, the laboratory failed to document room temperature and humidity for the TissueTek VIP Processor. This was noted for six out of eight months reviewed in 2022. The findings include: 1. A review of the environmental records revealed the laboratory failed to document room temperature and humidity for the room in which the TissueTek VIP was located in April, May, June, August, October, and November 2022. 2. A review of the TissueTek VIP Processor operating conditions reveals specifications, as follows: "Temperature: 10 to 40 degrees Celsius and Relative Humidity: 30 to 85%" 3. During an interview on August 29th, 2023, at 3:00 PM, the Laboratory Manager confirmed the above findings.