Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2151225	09/19/2019
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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Hologic Panther [used for the qualitative detection of Chlamydia trachomatis, Neisseria gonorrhoeae (CT/NG), Trichomonas vaginalis, and Human Papilloma Virus (HPV)] and interviews with the General Supervisor and the Laboratory Director, the surveyor determined the laboratory failed to ensure the APTIMA verification sample set (# 20520) was used for the validation of the instrument before their expiration date on 11/28/2019. The findings include: 1. Refer to D5421. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Hologic Panther

	and interviews with the General Supervisor and the Laboratory Director, the surveyor determined the laboratory failed to perform: (1) a valid verification of the manufacturer's performance specifications for precision and accuracy due to the use of expired verification samples, and (2) an evaluation of the data generated during the initial installation procedures for two out of four organisms, before patient testing began on 8/20/2019. The findings include: 1. A review of the installation and validation records for the Hologic Panther, used for the qualitative detection of Chlamydia trachomatis, Neisseria gonorrhoeae (CT/NG), Trichomonas vaginalis, and Human Papilloma Virus (HPV) revealed the Hologic Service Technician performed validation runs on 1/7, and 2/7 - 2/8/2019 (per instrument printouts) to establish the accuracy and precision of the analyzer. The surveyor reviewed the raw data from runs of positive (+) and negative (-) quality control samples, and "APTIMA Samples for Verification", specimens with known +/- results. However, a review of the manufacturer's assay sheet which specified the expected results, revealed the APTIMA Sample Set # 20520 used in the validation had expired on 11/28/2019 (approximately 6-10 weeks earlier). 2. A further review of the Panther records revealed the laboratory had analyzed and generated a chart of the expected results vs the actual results generated from the studies for CT/NG. However, there was no documentation the results for Trichomonas and HPV were analyzed and evaluated to verify the precision and accuracy as per manufacturer's performance specifications. The surveyor also noted there was no indication the Laboratory Director had reviewed and approved (as indicated by his signature and date) the initial verification procedures. [Refer to D6086.] 3. In an interview on 9/19/2019 at 12:40 PM, the above noted findings were reviewed and confirmed with the General Supervisor who stated they had not noticed the expiration on the APTIMA sample kit. The surveyor then asked if the analyzer had been used for patient testing. The Supervisor printed the records and stated four patients were tested for CT/NG and Trichomonas on 8/20 /2019, and one patient was tested for HPV on 8/29/2019. 4. During the exit summation with the Laboratory Director, the General Supervisor and the Toxicology Technical Supervisor on 9/19/2019 at approximately 3:30 PM, the surveyor reviewed the above noted findings, especially the invalid verification of the manufacturer's performance specifications for precision and accuracy due to the use of expired verification samples. .
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Hologic Panther [used for the qualitative detection of Chlamydia trachomatis, Neisseria gonorrhoeae (CT/NG), Trichomonas vaginalis, and Human Papilloma Virus] and interviews with the General Supervisor and the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure the laboratory performed: (1) a valid verification of the manufacturer's performance specifications for precision and accuracy due to the use of expired verification samples, and (2) an evaluation of the data generated during the initial installation procedures for two out of four organisms, before patient testing began on 8/20/2019. The surveyor further noted there was no indication the Laboratory Director had reviewed and approved (as indicated by his signature and

	date) the initial verification procedures for the analyzer. The findings include: 1. Refer to D5421. SURVEYOR ID #32558 Licensure and Certification Surveyor