Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2151225	10/01/2020
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
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on telephone interviews with complainants and laboratory staff, a review of policies and procedures, and a lack of documentation of resolution to the clients' concerns, the surveyor determined the laboratory failed to have an effective mechanism in place to ensure valid complaints are investigated and documented. This deficiency is a result of a complaint investigation, with complaint number (AL00039937) and conducted on October 1, 2020. The findings include: 1. The State Survey Agency received a telephone call from a staff member of a long-term-care residence in Alabama on August 26, 2020 at 10:45 AM. The staff member questioned the validity of the results of COVID 19 PCR (Polymerase Chain Reaction) testing by the reference laboratory. The staff member stated, after results were reported as positive, a retest on the following day, indicated the patient was COVID negative. According to the staff member from the long-term-care residence, the laboratory's Account Manager, in a telephone call, said the test media was contaminated; however, in another telephone call, a different staff member said there was no contamination. The occurrence of this, as well as several other questionable results, was in late June and up to August, 2020. During telephone calls on August 26 at 1:47 PM and 3:30 PM, and August 27, 2020 at 3:40 PM, several staff members from different locations of the same long-term-care corporation, reported questionable COVID 19 test results. The long-term-care staff stated the laboratory in question and corporate staff were working on resolving the issue, and would let the State Agency know the out-come. Resolution to the concerns were not communicated to the State Agency, prior to the survey entry on October 1, 2020. 2. Two surveyors entered the laboratory on October

	1, 2020, to investigate the allegations of concern. The surveyors toured the laboratory, with the Laboratory Director and Account Manager, where COVID testing was being performed, at approximately 10:00 AM. According to the Account Manager, the specimens were received, entered into the database/Laboratory Information System, labeled with a barcode, and tested in this area. The surveyors observed a staff member manually pipetting specimens, some potentially COVID positive, on-top the counter and without a biological hood. The surveyors also observed other instrumentation, including a Thermo Fisher Quant Studio 12. The transport from specimen processing to each instrument, as well as the mapping [orientation of specimen in the well (mapping = electronic scan in the barcode for well placement)] is done by hand. 3. On October 1, 2020 at 10:28 AM, in an interview with the Account Manager, Laboratory Director, and the surveyors, one surveyor asked if there had been any complaints of questionable test results, or of false positive or negatives. The Account Manager stated that from time to time, questions arise; and explained the cut off value for determining positive results. The surveyor inquired of the resolution to complaints, and if the laboratory could provide written documentation for surveyor review. The Account Manager recalled speaking to some long-term care clients, regarding concerns, however had not documented anything. The laboratory had no written record of the problems or documentation of resolution. At this time, the surveyor asked to review the policy and procedure for resolving issues and the quality assurance process. At 10:52 AM, when the Technical Supervisor (TS, also a testing personnel) joined the conversation, he stated he had retained several back-and-forth emails with the clients, but it would take some time (several days) to get them together for review. The TS also stated the laboratory could not provide any documentation of resolution to the problems or any trouble-shooting done to resolve the issues. 4. A review of the Quality Assurance Policy, provided by the Account Manager, revealed the following: "...Corrective Action Problems and Communication Breakdowns (page 43) Principle ...The purpose of the Corrective Action and Problem Log is to facilitate monitoring of various problems encountered within the lab and how they were addressed... Policy When any problem occurs concerning the laboratory, documentation must be recorded..." Items indicated in this policy, included turn-around-time problems, inconsistent results, and reported/received incorrect results. Another policy, page 9 (only the page was provided) indicated "...G. Communication Problems and Complaints 1. Communication Problems a. Evaluate communication for any breakdown between the laboratory, physician, and any other employees b. Document the problem and the solution 2. Complaints a. Record and evaluate between staff, physician, or other employees b. Remedial action is documented for all valid complaints..." .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on interviews during the entrance tour and during the survey process, and a review of proficiency testing (PT) records, the laboratory failed to document the investigation and corrective actions for failing PT scores until the day of the survey for one of one surveys reviewed. This deficiency is a result of a complaint investigation, with complaint number (AL00039937), conducted on 10/1/2020. The findings include:1. An unannounced survey was conducted on 10/1/2020 to investigate concerns voiced by a group of Nursing Homes regarding possibly

	erroneous results. During the entrance tour from 10-10:30 AM, the surveyor asked the Account Manager if the laboratory had received any client complaints regarding questionable COVID-19 results. The Account Manager stated he was confident in the laboratory's procedures, and explained to clients any discrepancies were due to the higher sensitivity of testing via PCR (Polymerase Chain Reaction). He further stated the laboratory had also completed one proficiency testing event, and had scored 100%. 2. After the entrance tour the surveyor requested the PT survey documentation at approximately 10:30 AM. The Account Manager stated the Technical Supervisor (TS) had the results on his computer, and could provide the records when he arrived. 3. At 10:50 the TS arrived and answered questions from the surveyors till approximately 11:30; the surveyors provided a list of documents they needed to review. At 12:00 PM, a surveyor approached the Manager and TS to ascertain the reason for the delay, and noted the Manager and TS were writing on the proficiency testing records. 4. At 12:15 PM the surveyor received the records for the CAP (College of American Pathologists) CoV2-A 2020 PT survey. PCR testing for COVID-19 was performed on three PT samples, however results for sample 1 and 2 were incorrect, resulting in a score of 33.3% (not 100% as the Account Manager had originally stated.). A note on the PT review form stated there was a clerical or sample mix-up, and samples were repeated on 7/13/2020. 5. During an interview on 10/1 /2020 at approximately 12:25 PM, the surveyor asked the TS when the original PT testing was performed; "on 6/4/2020", and when was evaluation received; the TS answered, "7/2/2020". The surveyor then expressed concern over the fact the above corrective action for the failure was not documented until the day of the survey. Furthermore, the laboratory had not documented how the error had occurred, or what measures were implemented to prevent recurrence. [However, when the surveyor requested copies of the PT records, the TS retroactively documented this information.] The TS stated the error occurred when he transcribed the instrument results into the CAP website late at night. The surveyor further explained since the complaint survey was being conducted to investigate the possibility of erroneous results for patients, the laboratory also needed to document a review of their procedures to ensure patient results were not affected. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a lack of quality assurance records and an interview with the Technical Supervisor (TS), the surveyor determined the laboratory failed to follow the Quality Assessment (QA) procedures. This deficiency is a result of a complaint investigation, with complaint number (AL00039937), conducted on 10/1/2020. The findings include: 1. An unannounced survey was conducted on 10/1/2020 to investigate concerns voiced by a group of nursing homes regarding possibly erroneous results. During the entrance tour from 10-10:30 AM, the surveyor asked the Account Manager if the laboratory had received any client complaints regarding questionable COVID-19 results. The Account Manager stated he was confident in the laboratory's procedures, however he stated more complex questions needed to be directed to the TS, who had not yet arrived at the laboratory. 2. At 10:50 AM the TS arrived and

	answered questions from the surveyors concerning the PCR (Polymerase Chain Reaction) testing process. The surveyor then asked how the viral transport media was validated, and what he would expect to see if the media was contaminated; the TC explained his validation process for each type of media, and stated contaminated media would produce "a bunch of positives". The surveyor asked if that had happened, and the TC answered, "Possibly...a couple of months ago". The surveyor asked for more information, and the TC explained he had reviewed a run after a "handful of results were questioned". The TC stated he noticed upon review that "all the results were just above or just below the equivocal range"; the samples above the cutoff were reported as positive for COVID-19. After noting this, he reran the positive samples, and all were negative. The surveyor then asked if this incident was documented, and if they had implemented corrective action to ensure the same scenario could not recur. Later at 12:45 PM, after reviewing his records, the TC confirmed he had not. . 3. A review of the policy, "Corrective Action Problems and Communication Breakdowns" ... "Policy When any problem occurs concerning the laboratory, documentation must be recorded." The surveyor also noted, "D. Proficiency Testing Assessment (PT) ... a. Remedial action is documented for each incorrect analyte. b. Remedial action is documented if less than 100%. E. Personnel Assessment ... 3. New employee evaluations are done at six months...". 4. During the exit summation at 12:55 PM on 10/1/2020, the surveyors explained their findings. Problems noted during the survey were a results of not following the laboratory's QA policies in the documentation of the problem and implementation of corrective actions to prevent recurrence, as follows: A) Failure to document test run problems (see incident above) B) Failure in proficiency testing (refer to D5221) C) Failure in communication with clients (refer to D5205), and D) Failure to document training and a semiannual competency evaluation for Testing Personnel #1 (refer to D6120). .
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 observations during the entrance tour, a review of personnel records and an interview with the Technical Supervisor, the laboratory failed to document training and the semi-annual competency evaluation for one of three Testing Personnel (TP) listed on the CMS-209. This deficiency is a result of a complaint investigation, with complaint number (AL00039937), conducted on 10/1/2020. The findings include: 1. An unannounced survey was conducted on 10/1/2020 to investigate concerns voiced by a group of Nursing Homes regarding possibly erroneous COVID-19 results. During the entrance tour from 10-10:30 AM, the Account Manager listed the general steps when performing PCR (Polymerase Chain Reaction) testing for COVID-19. The surveyors observed TP #3 "plating" patient samples from the viral transport media for the manual extraction phase. 2. A review of personnel records for TP #3 revealed she was hired 2/16/2020, and had an Associates of Science in Medical Laboratory Technology (MLT). However no training records or semi-annual competency evaluation were available. The Account Manager stated the Technical Supervisor

	(who had not arrived on site yet) would have these records. 3. At 10:50 the TS arrived and answered questions from the surveyors till approximately 11:30; the surveyors provided a list of documents they needed to review. At 12:15 PM some records were provided to the surveyors, however there were no training or competency records. The Technical Supervisor stated he had trained TP #3, but he been unable to locate those documents. SURVEYOR ID# 32558 Licensure and Certification Surveyor