Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2148969	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medical Diagnostic Laboratories	8238 S Madison St, Burr Ridge, IL	

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
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process. Findings include: 1. On 11/07/18 at 10:00 AM, the surveyor was given a tour of the laboratory. The laboratory was located in a corner within the same space as of 4 Path laboratory. A box which contained patients' records was stored on the floor beneath a desk with a computer that Medical Diagnostic Laboratories LLC used for accessioning . There was no lock on the box where patient's records were stored. 2. On 11/07/18 at 10:30 AM, testing personnel confirmed the surveyor's findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and test reports, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified

	problems for its mycology testing. Findings include: 1. Review of laboratory records revealed that the laboratory failed to establish performance specifications for it PCR testing for the detection of fungi. See D5423 2. There was no documentation to show that the laboratory took corrective actions when there were consistent problems with its record keeping. See D5791 3. The laboratory failed to document the address location of the laboratory performing the testing on its test reports. When the incorrect laboratory was recorded on test reports, there was no record of a corrected report
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation; review of the laboratory's testing menu; laboratory records; laboratory reports; and interview, the laboratory failed to establish performance specifications for its PCR procedures for the detection Candida albicans, Candida parpsilosis, Trichophyton rubrum, and Trichophyton interdigitale, for the following performance characteristics: A. Accuracy B. Analytic Sensitivity c. Analytical Specificity to include interfering substances. Findings include: 1. On 11/07/18 at 10: 00 AM, the surveyor was given a tour of the laboratory. The surveyor observed that the laboratory had 3 areas set up for testing, including reagent prep, specimen extraction, PCR amplification. PCR amplification was performed using 2 PCR analyzers (Rotor Gen Q and Rotor Gen 2). 2. Review of laboratory procedures manuals revealed that the laboratory tests for the following analytes using a test method that was developed by their laboratory: Candida albicans, Candida parpsilosis, Trichophyton rubrum, and Trichophyton interdigitale. 3. Review of laboratory records revealed that there was no actual raw data that shows that this laboratory established performance specifications for their laboratory developed test. The surveyor was just handed a chart with data. There was no documentation to show what the day to day runs; runs within runs, and/or operator variance were. In fact there was no documentation to show that testing personnel in this laboratory was included in the testing for establishing performance specifications. 4. Review of patients test reports revealed the following statement at the bottom of the reports: "A positive result is provided for bacteria, virus, and /or fungal species when PCR amplification (real - time PCR), sequence information (Pyrosequencing), and /or sequencing analysis occurs above cut-off levels established by the laboratory. Pertinent reference intervals for the tests reported above are available from the laboratory upon request." There was no documentation provided to the surveyor to prove this. 5. Review of 4 test reports revealed that test results were documented and final reports released prior to the laboratory establishing performance characteristics for 4 of 4 test reports reviewed. 6. On 11/07/18 at 4:00 PM, the laboratory director confirmed the surveyor's findings.

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 review of laboratory policies and procedures manuals and laboratory work sheets and interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, asses, and correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. Review of laboratory policies and procedures revealed that the laboratory had a written procedure that described the laboratory process for reviewing and assessing its laboratory testing. 2. Review of laboratory worksheets revealed that the laboratory had incorrect information on its worksheets for the "Master Mix" for the following: a. BIO-RAD iTaq SM 6.26 MM; 56.34 Total MM b. Canine F 0.13 MM; 1.17 Total MM c. Canine R 0.13 MM; 1.17 Total MM d. Canine Pr 0.13 MM; 1.17 Total MM e. H2O 4.62 MM; 41.56 Total MM f. DNA 1.25 MM; 11.25 Total MM Testing personnel crossed out the information documented on the worksheets for the "Master Mix", and wrote the following information instead: a. BIO-RAD iTaq SM 7.5 MM; 60 Total MM b. Canine F 0.125 MM; 1 Total MM c. Canine R 0.125 MM; q Total MM d. Canine Pr 0.125 MM; 1 Total MM e. H2O 4.625 MM; 37 Total MM f. DNA 1.25 MM; 11.25 Total MM (this remained the same) There was no documentation of any corrective actions when this was done, and no documentation to explain why the change was made. Records show that this was done on all worksheets since the laboratory started testing. 3. There was no documentation to show that the laboratory's analytical performance was evaluated by technical staff. 4. On 11/07/18 at 3:00 PM, the laboratory director confirmed the surveyor's findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review and interview, the test report did not indicate the name and address location of where the test was performed. Findings include: 1. Review of 4 patients' Final Test Results revealed that the name and address location of where the test was performed was not correctly identified on 1 of 4 patients' final report reviewed. One of 4 test reports had the name and address location of the lab's other location in Hamilton, NJ, and not the location in Burr Ridge, IL. There was no documentation to show that this test report was corrected, using the name and address location of the

	location in Burr Ridge, IL. 2. On November 7, 2018 at 3:30 PM, the laboratory director confirmed the surveyor's findings
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of testing worksheets and interview, the laboratory director failed to ensure that the quality assessment programs are established and maintained to identify failures in quality as they occur. 1. Review of laboratory worksheets revealed that testing personnel consistently changed information documented for the "Master Mix." Testing personnel crossed out information and hand wrote in different information on all worksheets. There was no documentation explaining why this was done and why this had not been corrected. 2. On 11/07/18 at 3:00 PM, the surveyor asked the laboratory director why nothing had been done to correct the incorrect information that was consistently recorded on laboratory worksheets. The laboratory director to the surveyor that she had not reviewed any of the analytical worksheets, and was not aware that there was a problem, confirming the surveyor's findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel records and interview, the laboratory director failed to ensure that testing personnel are competent and maintained their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings include: 1. Review of personnel records show that there was documentation of training for testing personnel performed by someone other than this laboratory. On 11/07/18 at 10:30 AM in an interview with the testing person, it was revealed that she was trained by their other laboratory which goes by the same name in Hamilton, NJ. 2. There was no documentation to show that the laboratory director, who is also listed as technical supervisor, assessed the competency of testing personnel, using the 6 competency assessment criteria, after they were initially trained. 3. On 11/07/18 at 10:30 AM, the laboratory director confirmed the surveyor's findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)

	The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures manuals; laboratory records; personnel records; and interview, the laboratory director failed to specify, in writing, the responsibilities and duties to each person involved in all phases of the testing process. Findings include: 1. Review of the laboratory's policies and procedures manuals revealed that there were procedures that stated that one of the laboratory director's responsibilities was to assign personnel to their positions held in the laboratory. 2. Review of Laboratory Personnel Report (CMS FORM 209) revealed that there were persons listed in the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor e. Testing Personnel 3. Review of personnel records revealed that the laboratory director did not assign any specific person(s) to the following positions in the laboratory: a. Laboratory Director (no one was named; only the duties and responsibilities of the position were listed). b. Clinical Consultant (no one was named; only the duties and responsibilities of the position were listed). c. Technical Supervisor 4. On 11/07/18 at 10:30 AM, the laboratory director confirmed the surveyor's findings.