Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2041165	02/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Discovery Diagnostic Laboratory	186 Cedar Hill St, Marlborough, MA	

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
D0000	A CLIA recertification survey was conducted for the Diagnostic Discovery Laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2116	TOXICOLOGY CFR(s): 493.845(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the College of American Pathologist (CAP) proficiency testing record review and interview, the laboratory failed to undertake appropriate remedial action in response to unsatisfactory proficiency testing results as evidenced by the following: a) A review of proficiency testing results for calendar years 2017 and 2018 (6 testing events) revealed that the laboratory obtained unacceptable scores for 7-aminoclonazepam in the Drug Monitoring for Pain Management module (DMPM B - specimen DMPM-07) for the second testing event of 2017 and benzoylecgonine and codeine for the third Forensic Toxicology testing event of 2017 (UDC D - specimen UDC-36). b) There was no documentation available of any remedial action taken in response to the unsatisfactory results. c) The laboratory general supervisor confirmed in an interview on 2/20/19 at 1:50 PM that remedial action in response to the unsatisfactory proficiency testing results had not been undertaken. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview on 2/20/19 at 9:20 AM with the general supervisor, the laboratory failed to verify the accuracy of analytes assigned a proficiency testing score that did not reflect laboratory test performance as evidenced by the following: a) A review of College of American Pathologist (CAP) proficiency testing results for calendar years 2017 and 2018 (six testing events) revealed that the proficiency testing service did not grade analyte results for amphetamine for the the second testing event of 2017 (UDSB-2017; specimens UDS 07 and UDS-08). b) There was no documented self grading performed by laboratory personnel for the above listed ungraded proficiency testing results. The general supervisor confirmed in an interview that ungraded proficiency testing results had not been addressed. .
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to assess preanalytic systems quality assessment activities as evidenced by the following: a) A review of the laboratory's preanalytical monitoring for calendar years 2017 and 2018 showed that the lab had policies and procedures for monitoring specimen and requisition problems. However, there was no ongoing assessment of these problems to identify trends or patterns that needed to be addressed and corrected. b) The general supervisor confirmed in an interview on 2/20/19 at 1:50 PM that there was no ongoing assessment of preanalytic system problems identified. .
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 record review and interview, the laboratory failed to ensure that conditions for reliable test system operation were appropriately monitored as evidenced by the following: a) A review of temperature and humidity monitoring records for calendar year 2017 and 2018 was performed. The review revealed that the humidity of the laboratory was consistently below the established range of 40 to 65 % room humidity up until May of 2018 when the acceptable humidity range was changed to 20 to 80% humidity. b) The general supervisors stated in an interview on 2/20/19 at 11:15 AM that the technical supervisor had contacted the manufacturer of the Liquid chromatography-tandem mass spectrometry (LC-MS/MS) to ascertain the appropriate humidity range for operating the analyzers. c) There was no documentation available at the time of the survey to verify the manufacturer's humidity requirements. In addition, there was no documented remedial action in response to the humidity results that were below the laboratory's established range of 40 to 65% humidity. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on procedure review and interview, the laboratory failed to follow their system that twice a year evaluated and defined the relationship between multiple analyzers performing the same type of testing as evidenced by the following: Three Agilent 6420 Triple Quadrupole Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) test systems: a) The laboratory performs confirmatory drug testing using three LC-MS-MS test systems. b) A review of the laboratory documentation for cross comparisons of the three analyzers revealed that the comparisons had been performed only once in 2017 (11/7/17) and 2018 (3/16/18). c) The general supervisor confirmed in an interview on 2/20/19 at 11;35 AM that cross comparisons between the three analyzers had only been performed once during 2017 and 2018. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to assess postanalytic systems quality assessment activities as evidenced by the following: a) A review of the laboratory's preanalytical monitoring for calendar years 2017 and 2018 showed that the lab had policies and procedures for monitoring post analytic problems. However, there was no ongoing assessment of these problems to identify trends or patterns that needed to be addressed and corrected. b) The general supervisor confirmed in an interview on 2/20/19 at 1:50 PM that there was no ongoing assessment of postanalytic systems problems identified.