Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0993149	11/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Molecular Diagnostic Laboratory Llc	950 Yale Avenue, Unit 39, Wallingford, CT	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain a copy of all proficiency testing (PT) records for a minimum of 2 years. Findings include: 1. Record review on 11/14/19 of the laboratory's 2018 and 2019 American Association of Bioanalysts (AAB) PT records revealed, the laboratory failed to maintain a copy of the worksheets for antibiotic sensitivity testing for AAB 2019 survey D for Q1, Q2 and Q3 events. 2. Staff interview with the laboratory director on 11/14/19 at 11:00 AM confirmed the above findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure positive identification of a patient's specimen from the time of collection through completion of testing. Findings include: 1. Record review of the human chorionic gonadotropin (HCG) quantification instrument printout on 11/14/19 revealed the following: a. On 11 /5/19, one patient sample was labeled with first letter from patient's first and last name. b. On 10/18/19, one patient sample was labeled with first name only and three more samples were labeled with first letter from the patient's first and last name. Two more samples were labeled with first letter from the patient's first name. 2. Staff interview on 11/14/19 at 11:05 AM with the laboratory director (LD) confirmed the above findings. The LD stated it is more confusing for him/her to use the accession number and that is why letters from the patient's name were used while testing samples. 3. The laboratory performs 376 HCG quantification tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to comply with the manufacturer's maintenance recommendations. Findings include: 1. Record review on 11/14/19 of the equipment(s) preventive maintenance (PM) log revealed annual PM of the Biological Safety Cabinet (Serial # 2S-15-B-6482) was not performed in 2018. The manufacturer's recommendation revealed annual PM is required for the proper functioning of the equipment. 2. Staff interview the laboratory director on 11/14/19 at 12:15 PM confirmed the above findings. The LD stated it is difficult to get the technician to perform PM of the equipment.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to

	identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform calibration verification for human chorionic gonadotropin (HCG) quantification test in the required frequency. Findings include: 1. Record review on 11/14/19 of the calibration verification records for the laboratory's Biomerieux mini-vidas analyzer used to perform HCG quantification test revealed the last calibration verification was performed on 12/19/17. 2. Record review on 11/14/19 of the Biomerieux mini-vidas analyzer operator's manual revealed calibration verification must be performed every six months. 3. Staff interview with the laboratory director (LD) on 11/14/19 at 11:20 AM confirmed the above findings. The LD stated calibration verification materials are costly. 4. The laboratory performs 376 HCG quantification tests annually.