Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0993149	04/13/2022
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to verify the accuracy bi-annually for the Urinalaysis test under the specialty of Chemistry. Findings include: 1. Surveyor observation on 04/13/2022 at 11:50 AM revealed the laboratory is using an instrument to perform Urinalysis test by Bayer Clinitek 100, Model # 5772, Serial # 124745. 2. Record review of the laboratory's proficiency testing (PT) documents on 4/13/2022 revealed: a. Lack documentation of bi-annual verification of accuracy of the urinalysis(UA) tests. b. Lack of documentation that the laboratory was enrolled in a PT program for UA tests. 3. Staff interview with laboratory director (LD) on 04/13/2022 at 12:10 PM confirmed: a. The laboratory did not enroll in the PT program for UA. b. The LD further stated he/she was under the impression the instrument used to perform the UA was a waived instrument. c. The last time Biannual accuracy verified was in 2015. 4. The laboratory performs 50 UA annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to label controls with the appropriate expiration dates in the subspecialty of endocrinology. Findings include: 1. Surveyor observation of the BioMerieux Vidas hCG Reagent kit, on 04/13/2022 at 10:45 AM revealed the following: a. Bio-Rad Lypochek Immunoassay Plus(BLIP) controls Level 1,2 and 3, lot # 40411, 40412 and 40413 respectively, with an expiration date of 9-30-2024 were reconstituted and in use and stored at 2 to 8 degrees Celsius. b. All the three levels of control listed above lacked the documentation when they were opened/reconstituted and date of expiration on the bottles. 2. Record review of the BLIP controls package insert 04/13/2022 revealed "when reconstituted and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: All analytes: 7 days, Except: Folate and PSA(Total): 3 days, C-Peptide: 1 day and ACTH, Calcitonin, Gastrin and PSA(Free): assay immediately after reconstitution." 3. Staff interview with Laboratory Director on 04/13 /2022 at 11:59 AM confirmed that he/she was not aware of the change in expiration dates once the control materials were reconstituted. 4. The laboratory performs 559 hCG tests annually.
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 record review and staff interview the laboratory failed to report the the human Chorionic Gonadotropin (hCG) results within the established analytical range provided by manufacturer in the sub specialty of Endocrinology. Findings include: 1. Record review on 4/13/2022 of the Vidas HCG(HCG) package insert in the "Results and Interpretation" section revealed: "a. Samples with concentration greater than 1500 mIU/mL maybe reassayed after diluting by 1/20 to 1/200. b. If the dilution factor has not been entered when the analysis has been requested, multiply the result by the dilution factor to obtain the hCG concentration." 2. Record review on 4/13/2022 of a written email communication with the Technical Specialist at BioMerieux confirmed the reportable technical range for hCG to be 2 to 300,000 mIU/mL, and any values greater than the reportable range to be resulted as "greater than 300,000 mIU/mL". 3. Record review on 4/13/2022 of a patient report for the hCG test performed on 1/27 /2022 revealed: a. The instrument printout displayed dilution of 1:200 was performed and the result obtained was 2244.93 mIU/mL. b. The laboratory reported the above hCG results as : "448,800 mIU/mL". 3. Staff interview with the Laboratory Director on 4/13/2022 at 11:47 am confirmed: a. The technical reportable range for the hCG was 2 to 300,000 mIU/mL. b. The result (2244.93) obtained on the patient was multiplied by 200 and the value (448,800) was resulted. 4. The laboratory performs approximately 559 hCG tests annually.
D5537	ROUTINE CHEMISTRY

	CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test control material for positive and negative reactivity every day of testing, and when opening a new bottle of Siemens Multistix 10 SG Urine Reagent strips in the subspecialty of Urinalysis. Findings include: 1. Record review on 04/13/2022 of the manufacturer package insert for the Siemens Multistix 10 SG revealed under the "Quality Control" section: "Test known negative and positive specimens or controls whenever a new bottle is first opened." 2. Record review on 04/13/2022 of the Siemens Multistix 10 SG QC Record log for 2020 and 2021 revealed lack of documentation for the positive and negative control performed with each new bottle opened, each day of testing or every 8 hours. 3. Staff interview with laboratory director on 04/13/2022 at 12:10 PM confirmed that the last time the QC was performed on the instrument was in 2015. 4. The laboratory performs 50 urine analysis tests annually.