Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0938580	(X3) Date Survey Completed 08/01/2023
Name of Provider or Supplier Long Island Medical Laboratory	**Street Address, City, State** 393 Old Country Road, Carle Place, NY	

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	An announced CLIA exempt-state validation survey was conducted at Long Island Medical Laboratory (dba Mount Sinai Doctors LIHA) on August 01, 2023 by CMS Boston CLIA federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with standard-level CLIA requirements.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review, laboratory written standard operating procedures, and interview with the Laboratory Director (LD), the laboratory failed to follow the laboratory's standard operating procedure to ensure the laboratory centrifuge was functioning properly for one of one centrifuge. Findings include: 1. Interview on 08/01/2023 at 10:00 AM with the LD, confirmed the laboratory performed patient testing using the Beckman Coulter AU480 analyzer and the Beckman Coulter Access 2 Analyzer. 2. Interview on 08/01/2023 at 11:14 AM with the LD, confirmed the laboratory began patient testing at the current location on 04/07/2023. 3. On 08/01/2023, a review of the laboratory's written standard operating procedures: a. "SOP MANUAL CLINICAL CHEMISTRY AND ENDOCRINOLOGY" under section "Blood Collection Tubes" stated, "When blood is collected into red-or marble-top tube DO NOT SHAKE THE TUBE. The blood in the tube may be permitted to clot for 20-30 min at room temperature. When a clot is formed, a serum is produced and collected after centrifugation (10 min at 3000 rpm, room temperature)." b. "SOP MANUAL III. LABORATORY EQUIPMENT AND SUPPLIES" under section "Procurement and

	Installation" stated, "Laboratory equipment is: a) selected and upon installation it checked to ensure that is capable of achieving the performance required; b) uniquely marked, or otherwise identified and properly referenced in records of maintenance, function checks and performance assessment; c) labeled to indicate the status of calibration or verification due date;" 4. On 08/01/2023, a review of the centrifuge function check records revealed no evidence the centrifuge was checked for performance before put into use on 04/07/2023. 5. Interview on 08/01/023 at 02:10 PM with the LD, confirmed the above the findings.
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: A. Based on record review, manufacturer's instructions, and interview with the Laboratory Director (LD), the laboratory failed to ensure the laboratory humidity was maintained as required by the manufacturer of the Beckman Coulter AU480 (serial number #2022110236) analyzer for three of three months. Findings include: 1. Interview on 08/01/2023 at 09:10 AM with the LD, confirmed the laboratory performed chemistry testing using the Beckman Coulter AU480 (serial number #2022110236) analyzer. 2. On 08/01/2023, a review of the manufacturer's "2.2 Installation Environment Precautions" under section "Temperature and Humidity Conditions When in Use" stated, "The humidity is between 20% RH and 80% RH with no condensation". Relative Humidity (RH). 3. On 08/01/2023, a review of laboratory temperature records from May 2023 through July 2023 revealed no evidence of humidity readings for three of three months. 4. Interview on 08/01/2023 at 01:50 PM with the LD confirmed the above findings. B. Based on record review, observation, manufacturer's instructions, and interview with the Laboratory Director (LD), the laboratory failed to ensure freezer temperatures were maintained as required by the manufacturer for four of four months. Findings include: 1. Interview on 08/01 /2023 at 10:00 AM with the LD, confirmed the laboratory performed patient testing using the Beckman Coulter AU480 analyzer and the Beckman Coulter Access 2 Analyzer. 2. Interview on 08/01/2023 at 11:14 AM with the LD, confirmed the laboratory began patient testing at the current location on 04/07/2023. 3. Observation on 08/01/2023 at 02:15 PM of the material in the laboratory freezer identified the following materials: a. Access Prolactin Calibrator Lot #234435, the storage requirement as stated on the box required a storage temperature of -20C or colder b. Access Progesterone Calibrator Lot #234436, the storage requirement as stated on the box required a storage temperature of -20C or colder c. Access hLH Calibrator Lot #234081, the storage requirement as stated on the box required a storage temperature of -20C or colder d. Access BNP Calibrator Lot #234518, the storage requirement as stated on the box required a storage temperature of -20C or colder e. Bio-Rad Liquid MultiQual Lot #45951, the storage requirement as stated on the bottle required a storage temperature between -20C to -70C f. Bio-Rad Liquid MultiQual Lot #45953, the storage requirement as stated on the bottle required a storage temperature between

	-20C to -70C 3. On 08/01/2023, a review of freezer temperature records from April 2023 through Jul 2023 revealed freezer temperatures too warm for four of four months as follows: a. April 2023 - Specific days freezer temperatures documented warmer than -20C (Days 3,4,5,6,7,10,11,12,13,14,17,18,19,20,21,24,25,26,27,28) b. May 2023 - Specific days freezer temperatures documented warmer than -20C (Days 1,2,3,4,5,8,9,10,11,12,15,16,17,18,19,22,23,24,25,26,29,30) c. June 2023 - Specific days freezer temperatures documented warmer than -20C (Days 1,2,5,6,7,8,9,12,13,14,15,16,19,20,21,22,23,26,27,28,29,30) d. July 2023 - Specific days freezer temperatures documented warmer than -20C (Days 3,5,6,7,10,11,12,13,14,16,17,18,19,20,21,24,25,26,27,28,31) 4. Interview on 08/01 /2023 at 02:15 PM with the LD confirmed the above findings. C. Based on record review, observation, and interview with the Laboratory Director (LD) and clinic phlebotomist, the laboratory failed to ensure blood collection tubes were stored as required by the manufacturer for three of three months. Findings include: 1. Interview on 08/01/2023 at 09:50 AM with the Laboratory Director (LD), confirmed the laboratory performed Complete Blood Count (CBC) testing from EDTA vacutainer tubes on the Cell Dyn 1800 analyzer. 2. Observation on 08/01/2023 at 04:20 PM in Phlebotomy Room #1 and Phlebotomy Room #2 identified the following materials: a. Phlebotomy Room #1 - BD Vacutainer K2 EDTA 100 tubes Lot #3111819 b. Phlebotomy Room #2 - BD Vacutainer K2 EDTA 100 tubes Lot #2321388 3. On 08 /01/2023, a review of the manufacturer's storage requirement located on the packaging of unopened containers of blood collection tubes, identified a 4 - 25C manufacturer storage temperature requirement. 4. On 08/01/2023, a review of temperature records from May 2023 through July 2023 for Phlebotomy Room #1 and Phlebotomy Room #2 revealed no evidence of room temperature readings for three of three months. 5. Interview on 08/01/2023 at 04:30 PM with the clinical phlebotomist confirmed the above findings.