Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0156638	10/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lewin, Fagen & Lown, Md Pc	2171 Jericho Turnpike, Suite 100, Commack, 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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on the lack of humidity log, the laboratory failed to monitor humidity and room temperature since implementation February 2021 through survey date as required by Horiba Pentra 400 and Horiba Micros 60. Finding: 1. Horiba Pentra 400: Humidity 20-85%, Room Temperature 59F-90F (15?-32?) 2. Horiba Micros 60: Humidity 20-80%, Room Temperature 65F-90F (18?-32?) 3. Confirmed on an interview with practice manager on 10/14/2022 about 11:30am.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Horiba Micros 60 and Horiba Pentra 400. FINDINGS: 1. The new QC lot to lot validation documentations of hematology analyzer were not available upon request during the survey since the hematology analyzer implementation date to survey date. 2. The laboratory director confirmed during interview on 10/14/2022 at 11am, the new lot to lot validation of QC material for Horiba Micros 60 and Horiba Pentra 400.