Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0869932	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lagrange Internal Medicine	1602 Vernon Road Suite 400, Lagrange, GA	

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 recertification survey was performed on May 8, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of correlating patient data for the Quality Control (QC) failures documented and staff interviews revealed that not all QC were reviewed and acceptable on each day of the QC failures. Cholesterol (CHOL) patient testing was performed and resulted on dates in which QC failed. Findings: 1. A review of patient data on November 13, 2023 revealed all levels of CHOL failed >2 SD with no corrective action taken. 2. Patient records for November 13, 2023, showed that 83 patients were tested and resulted. The following Patient's were ran and resulted: 53101; 75145; 83703; 77335; 67350; 86022;30404; 84481; 73421; 71166; 37267; 55472; 72289; 54804;25248; 58752; 7428; 40138;71903; 27145; 84110; 27248; 78000; 25516; 66872; 53100; 82199; 22601; 34367; 21569;81945; 25191; 28669; 52581; 33015; 72310; 65413; 34488;75694; 71415; 19757; 87033; 62941; 67107; 21869; 22400;73661; 74938; 54119; 17674; 54682; 74115; 55460; 50313;69679; 86101; 58216; 68107; 63046; 13516; 64299; 51518;13022; 73193; 80975; 80072; 72748; 73092; 77836; 22326; 64214; 15916; 01269; 66186; 86660; 22721; 73841; 24581;58098; 5951; 28675; 33793; and 85964. 3. Interviews with the lab director and technical consultant (CMS 209) on 5/8/24 at 2:30 PM in the small conference room, confirmed the aforementioned findings.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on Chemistry Quality Control (QC) document review and staff interviews, the laboratory failed to document corrective actions when QC was out of limits on the Cobas 6000. Findings: 1. Review of QC for the Cobas 6000 revealed Cholesterol QC values were out of the laboratory's established range on all levels for the date of 11/13 /2023. There were 83 patients resulted on this date. 2. No corrective actions were available to review on 11/13/24 to address the out of range QC. 3. Interviews with the technical consultant (CMS form 209) and the lab director (CMS 209) in the small conference room on 5/8/24 at 2:30 PM, confirmed the lack of corrective actions for QC out of range on the aforementioned date.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: The review of Quality Control (QC) Records for January 2023, June2023, November 2023, and February 2024 as well as interviews with the lab director (LD) and technical consultant (TC) revealed the LD failed to ensure QC was within the laboratory's acceptable ranges before releasing patient data. Findings: Refer to 5783