Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0147933	07/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Goldberg & Pellegrini Md, Pc	380 88th Street, Brooklyn, 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
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 surveyor's review of laboratory's equipment maintenance procedures, lack of maintenance records for the Alfa Wasserman Ace chemistry, Beckman Coulter AcT Diff hematology, Beckman Access 2 endocrinology analyzers and an interview with the testing person, the laboratory failed to follow the manufacturer's requirements and the laboratory's maintenance procedures for the analyzers from January 1, 2021 through July 13, 2021. FINDINGS: 1. The testing person confirmed on July 13, 2021 at approximately 10:00 AM, the laboratory failed to follow the manufacturer's requirements and the laboratory's maintenance procedures for the Alfa Wasserman Ace chemistry, Beckman Coulter AcT Diff hematology, Beckman Access 2 endocrinology analyzers from January 1, 2021 through July 13, 2021. a. The laboratory failed to perform the weekly, monthly and quarterly maintenance as required.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible,

	traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor's review of Beckman Coulter AcT Diff hematology analyzer records and an interview with the testing person,the laboratory failed to perform the required six-month calibration for the Beckman Coulter AcT Diff analyzer due on January 1, 2021. FINDINGS: The testing person on July 13, 2021 at approximately 10: 00 AM, that the laboratory did not perform the required six month calibration for the hematology analyzer due in January 2021. a. The laboratory's calibration policy and the manufacturer policy for the Beckman Coulter AcT Diff hematology analyzer requires the analyzer to be calibrated every six months and/or as needed after preventative maintenance. b. The calibration was due January 1, 2021 therefore, the analyzer was out if calibration from January 1, 2021 through survey date July 13, 2021. c. Approximately 150 patient specimens were tested and reported for hematology during the time period when analyzer was out of calibration.
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 surveyor's review of the laboratory's calibration and calibration verification procedures, lack of calibration verification records and an interview with the testing person, laboratory failed to perform the six-month calibration verification for the Alfa Wasserman ACE chemistry analyzer due on January 1, 2021. FINDINGS: 1. The laboratory testing person confirmed on July 13, 2021 at approximately 10:30 AM, laboratory failed to perform the six-month calibration verification for the Alfa Wasserman ACE chemistry analyzer due in January 1, 2021. a. the laboratory did not perform the required calibration verification for those test analyte's that have less than

	3-point calibrator. The chemistry analyzer performs a 1-point calibrator Gemcal as required, therefore, calibration verification is required every six-months. b. Approximately 175 patients were tested and reported during this time period.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory maintained the laboratory's QC program for chemistry and hematology. Refer to D6020
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of chemistry and hematology QC records and confirmed in an interview with the laboratory testing person at the time of this survey, the laboratory director failed to ensure that the QC program for chemistry and endocrinology was maintained to assure the quality of laboratory services. Refer to: D5437 and D5439.