| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>33D0147933 | (X3) Date Survey Completed<br>04/26/2023 |
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| **Name of Provider or Supplier**<br>Goldberg & Pellegrini Md, Pc | **Street Address, City, State**<br>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 |
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| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on of the laboratory's calibration and verification procedures, lack of calibration verification documentation, and an interview with the testing person, the laboratory failed to perform the Alfa Wasserman ACE chemistry analyzer six-month calibration verification due on January 1, 2021. FINDINGS: 1. The laboratory's calibration verification procedure required calibration verification to be performed for test analytes that have less than three point calibrator. It was noted that the Gemcal |

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| | one point calibrator was performed on the chemistry analyzer however calibration verification was required every six-months. 2. The laboratory failed to perform calibration verification from 3/5/2022 through 4/24/2023. It was noted that calibration verification was performed from 2/5/2021 and 4/24/2023. Approximately 200 patients were tested from 3/5/2022 through 4/24/2023. 3. The laboratory testing person confirmed on April 26, 2023, at approximately 3:30 P.M. that the laboratory failed to perform the Alfa Wasserman ACE chemistry analyzer six-month calibration verification for 3/5/2022 through 4/24/2023. Refer to D6000 and D6020. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON JULY 13, 2021 |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's calibration verification procedure and confirmed in an interview with the testing person, the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Implemented and maintained the plan of correction from the survey conducted on July 13, 2021. 2. Maintained the QC program for chemistry testing, refer to D6020. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON JULY 13, 2021. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Alfa Ace Wasserman operations manual, the laboratory's calibration verification records, and an interview with the testing person, the laboratory director failed to maintain the chemistry QC program to ensure the quality of laboratory services performed. Refer to D5439. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON JULY 13, 2021. |