

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0147933	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Goldberg & Pellegrini Md, Pc	Street Address, City, State 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory records for the GenBio Immuno-DOT Antinuclear Antibody (ANA) and the Biokit rheumajet Rheumatoid Factor (RF) - Latex Agglutination test kit, and an interview with the laboratory testing person, the laboratory failed to document the quality control results for the above kits. FINDINGS: 1. The testing person confirmed on September 5, 2018 at approximately 11:00 AM, that quality control records for the ANA testing from July 20, 2016 to May 8, 2017 and RF testing from July 20, 2016 to September 5, 2018 were not available for review at survey. 2. The Biokit rheumajet RF -Latex Agglutination test kit requires that the positive and negative controls (included in the test kits) be performed to ensure that the latex reagent is performing properly for accurate and reliable testing. 3. The ImmunoDot ANA Screening panel test kit used by the laboratory for ANA testing requires that the positive and negative controls be performed to ensure that the reagents are active for accurate and reliable testing. Approximately 125 patient samples were tested and reported for ANA and 55 patient samples were tested and reported for RF. With your plan of correction, please include a copy of the form on which you have documented the positive and negative quality control results for the RF testing. THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON July 20, 2016; June 26, 2014; and August 8, 2012.</p>
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 the surveyor's review of laboratory records and an interview with the testing person, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure that: 1. The plan of correction from the surveys conducted on July 20, 2016 was maintained. 2. The QC program for general immunology testing was maintained, refer to D6020. THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON July 20, 2016; June 26, 2014; and August 8, 2012.

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 the surveyor's review of the laboratory's quality control (QC) records, and confirmed in an interview, at the time of this survey, with the laboratory testing person, the laboratory director failed to ensure that the QC program for general immunology testing was maintained to assure quality of laboratory services. Refer to: D5449. THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON July 20, 2016; June 26, 2014; and August 8, 2012.