Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2008783	03/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Professional Gynecological Services, Pc	14 Dekalb Avenue, 2nd Floor, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's procedure manual, Bio-rad Unity Peer Review reports for 2017 & 2018, QC file for the Siemens DPC Immunlite 2000 in Laboratory Information System (LIS), GeneXpert DX system and an interview with the technical consultant/testing person, the laboratory failed to retain chemistry, endocrinology, general immunology, syphilis screening and bacteriology quality control (QC) records and QC & calibration control Bio-rad assay sheets from January 2, 2017 through March 12, 2019. FINDINGS: 1. The current technical consultant /testing person confirmed on March 12, 2019 at approximately 11:00 AM the surveyor's findings that the laboratory failed to retain chemistry, endocrinology, general immunology, syphilis screening and bacteriology QC records and QC & calibration control Bio-rad assay sheets from January 2, 2017 through March 12, 2019. The following number of patient samples were tested and results reported for these specialties during the above time-period: a. approximately 780 patient samples for bacteriology b. approximately 1500 patient samples for both chemistry and endocrinology c. approximately 1000 patient samples for both syphilis screening and general immunology 2. The current technical consultant/testing person stated, "that he only keeps a current lot of QC raw data in the LIS LABDAQ software system and deletes the QC data after he enters the results to Bio-rad Unity QC Peer Review program" 3. Surveyor could not determine if the QC raw data entered into the Bio-rad system was accurate due to the lack of QC packet inserts. 4. The laboratory's

	information system (LIS) using LABDAQ software was down during this survey and the records were not available for review of the current lot of controls for the Immunlite 2000 and GeneXpert analyzers.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review the American Proficiency Institute (API) Proficiency Testing (PT) records on-line in the LABDAQ system, observed College of Pathologist (CAP) PT report and interview with the technical consultant/testing person, the laboratory failed to retain API & CAP PT records and documentation to include signed attestation forms, instrument printouts and a signed PT summary reports for the 3rd event of 2017, all three events in 2018 and 1st event of 2019. FINDINGS: The technical consultant/testing person confirmed on March 12, 2019 at approximately 11: 15 AM the surveyor's findings that the laboratory failed to retain API & CAP PT records and documentation to include signed attestation forms, test results & instrument printouts and a signed PT summary reports for the 3rd event of 2017, all three events in 2018 and 1st event of 2019.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of API PT summary reports on-line and an interview with the technical consultant/testing person, the laboratory failed to evaluate 3rd event of 2017, all three events in 2018 and 1st event of 2019 PT summary reports; perform and document remedial action for the PT scores of less than 100% and for the following analytes: 2018 first event: Thyroid Stimulating hormone (TSH)= 80% Endocrinology = 93% 2018 third event: Thyroid Stimulating hormone (TSH)= 80% Endocrinology = 93%
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the technical consultant/testing person, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2017 and 2018 calendar years.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a lack of humidity records, room temperature records, refrigerator temperature logs an and interview with the technical consultant/testing person, the laboratory failed to follow the manufacturer's instructions for the GeneXpert DX bacteriology test system to monitor and document the room humidity, room temperature and to take corrective action for out of range refrigerator temperatures from February 1, 2019 through March 12, 2019. FINDINGS: 1. The technical consultant/testing person confirmed on March 12, 2019 at approximately 10:30 AM, that the laboratory failed to follow the manufacturer's written criteria to monitor and document the humidity of the room (10-80%) and room temperatures (15-30 C) for the GeneXpert DX system for bacteriology testing from December 18, 2017 through March 12, 2019. 2. No corrective action documentation was available for review for the out of range refrigerator temperatures from February 1, 2019 through March 12, 2019. a. the recorded range for this time period was from 11-15 F; the established range was 2-8C or 36-45 C
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a surveyor's review of the validation records for the first GeneXpert DX bacteriology system and an interview with the technical consultant/testing person, the laboratory failed to perform and document a complete method validation for the second GeneExpert DX system prior to patient testing in February 2018. FINDINGS: 1. The technical consultant/testing person on March 12, 2019 at approximately 10:30 AM confirmed that validation study for the GeneXpert DX system (S/N 819386) installed on February 18, 2018 was not performed, prior to patient testing. 2. The laboratory failed to evaluate and implement (sign & date) the validation study performed for the GeneXpert system (S/N 818250). 3. Approximately 780 patient specimens were tested and reported for N. gonorrhea and Chlamydia.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor' review of the GeneXpert QC requirements, lack of a Individualized Quality Control Plan (IQCP) procedure and an interview with the technical consultant/testing person, the laboratory failed to have a complete IQCP for Bacteriology testing. FINDINGS: The surveyor established on March 12, 2019 at approximately 11:30 AM, that the laboratory is not performing external controls for the GeneXpert analyzers and failed to establish IQCP procedures for each instrument, which consists of a Quality Control Procedure (QCP), Quality Assessment Procedure (IQAP) and Risk Assessment Procedure (RA) for the two GeneXpert DX bacteriology systems for N. gonorrhea and Chlamydia testing. a. The laboratory is performing only internal controls each day of testing for GeneXpert DX Analyzers (S/N 818250) and (S /N 819386).
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's review of the laboratory's established policies & procedures, laboratory records and an interview with the technical consultant/testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory; 1. reviewed the scored proficiency testing reports received from API and CAP, refer to D6018; 2. establish an IQCP for the GeneExpert DX bacteriology system, refer to D6020; 3. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on the surveyor's review of API and CAP proficiency testing reports and an interview with the technical consultant/testing person, the laboratory director failed to review (sign and date) the scored proficiency testing reports received from API and CAP to evaluate the laboratory's performance. Refer to D3037 and D5211
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 Bio-rad Unity Peer Review QC records and confirmed in an interview with the technical consultant/testing person, the laboratory director failed to ensure that the QC program for bacteriology, syphilis, general immunology, chemistry and endocrinology testing was maintained to assure quality of laboratory services. Refer to: D3031, D5421 and D5445
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's QA policy and an interview with the technical consultant/testing person, the laboratory director failed to follow their QA procedure for having an on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for bacteriology, immunology, endocrinology and chemistry in the calendar years 2017 and 2018. Refer to: D5211, D5291, D5413, D5421 and D5445