Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2163821	11/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
David Abayev Gynecology Pc	104-20 Queens Blvd - Apt 1b, Forest Hills, 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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the laboratory consultant and the testing person, the laboratory failed to document the date and time that the specimens are received in the laboratory. Findings Include: 1. The technical consultant and the testing person confirmed in an interview on November 26, 2019, at approximately 12:30 PM that the receipt date and time of specimens are documented. 2. The specimen is taken at the doctor's office located at 104-40 Queens Blvd and transported to the laboratory located at 104-20 Queens Blvd. 3. Approximately 10 test requisitions forms were reviewed, and they failed to include receipt date and time.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of procedures and an interview with the technical consultant and the testing person, the laboratory failed to monitor and evaluate the overall quality system and prevent problems from occurring for the following: 1. Ensure that the

	laboratory had a complete procedure manual. Refer to D5403; 2. Ensure that storage freezer temperatures are within the acceptable range. Refer to D5413 3. Ensure that validation procedures are performed. Refer to D5421
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the technical consultant and the testing person, the laboratory failed to have a complete procedure manual for all testing. Findings Include: It was confirmed with the technical consultant and the testing person on November 26, 2019, at approximately 10:30 am that the laboratory failed to have the following procedures: 1) Patient preparation, specimen collection, specimen labeling, storage and preservation, transportation, processing, acceptability, rejection, and referral. 2) Quality control criteria (procedures). 3) Step-by-step performance of the procedure, including test calculations and interpretation of results. 4) Preparation of calibrators, controls, reagents, stains, and other materials used in testing. 5) Calibration and calibration verification procedures. 6) The reportable range for test results for the test system as established. 7) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 8) Limitations in the test methodology, including interfering substances. 9) Reference intervals (normal values). 10) Imminently life-threatening test results, or panic or alert values. 11) Pertinent literature references (Package inserts). 12) Entering results in the patient record and report patient test results. How does the lab report imminent life-threatening results, or panic, or alert values? 13) Actions to be taken if a test system becomes inoperable. 14) A procedure for the batched test.
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 review of the storage refrigerator temperature records, and an interview with the technical consultant and the testing person, the laboratory's storage freezer temperature failed to have a reading of -20 degrees Celsius or lower as required by the manufacturer. Findings Include: 1) The technical consultant and the testing person confirmed on November 26, 2019, at approximately 1:45 PM that the package inserts stated the freezer temperature for Free T 4, Prolactin, Progesterone, Foliate, GI Monitor and Beta hCG calibrators are to be stored at -20 degrees Celsius. 2) A review of the documented freezer temperature record indicated that the freezer temperature ranged -16 - (-19) degrees Celsius for the following: a) 6 of 11 days of patient testing in August 2019. b) 8 of 12 days of patient testing in September 2019. c) 9 of 11 days of patient testing in October 2019. d) 3 of 10 days of patient testing in November 2019. 3) Approximately 32 patient specimens were tested and results released during that time.
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 review of instrument validation records and an interview with the technical consultant and the testing person, the laboratory failed to have records for the validation of the ABX Pentra 400 chemistry analyzer. Findings Include: It was confirmed with the technical consultant and the testing person on November 26, 2019, at approximately 12:00PM that the laboratory failed to perform and have documentation available for review for the linearity (the reportable range) of the ABX Pentra 400 chemistry analyzer. Approximately 32 patient specimens were tested, and results released since testing began in August 2019.
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 findings and an interview with the technical consultant, the

	laboratory director failed to provide overall management of the laboratory. Refer to D6021, D6030, and D6032
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 a review of QA procedures, reviews and an interview with the testing person, the director failed to ensure that the laboratory's QA program for the laboratory was maintained for all phases of laboratory testing. Refer to: D5313, D5403, D5413 and D5421
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of personnel procedures and an interview with the technical consultant, the laboratory failed to have policies and procedures. Findings Include: It was confirmed with the technical consultant that the director failed to have in place a policy and procedure to determine the competency of the technical consultant.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

	review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of personnel records and confirmed in an interview with the technical consultant, the laboratory director failed to specify, in writing, the duties and responsibilities for two of two technical consultant staff involved in all phases of laboratory testing.