Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0714183	01/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Greater Binghamton Obstetrics & Gynecology, Pllc	365 Harry L Drive, Suite 110, Johnson City, 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
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 a surveyor's review of Quality Assessment (QA) policy and confirmed in an interview with the laboratory testing person, the laboratory failed to follow their written QA policy for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing. FINDINGS: The laboratory testing person confirmed on January 29, 2021 at approximately 10:00 AM, the surveyor's findings that the laboratory did not follow the QA policy and perform an annual QA review for the calendar years 2019 and 2020, as required by their QA policy. Refer to D5417
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation, review of the patient urinalysis & urine pregnancy log sheets and an interview with the testing person, the laboratory failed to ensure that the McKesson Consult Diagnostic positive/negative urine controls and the

	Quantimetrix Urine Dipper Controls were not used when they exceeded their expiration dates. FINDINGS: The testing person confirmed on January 29, 2021 at approximately 9:00 AM the surveyor's findings, the surveyor observed urine control materials, in the laboratory refrigerator, had exceeded their expiration dates. 1) McKesson Consult Diagnostic positive/negative pregnancy control Lot # CC00456 with expiration date of 11-30-20 2) Quantimetrix Urine Controls Level #1 Lot # 44791 and Level 2 Lot # 44792 with expiration dates of 11-30-20 3) Surveyor could not determine if the current Clarity urine pregnancy tests kit and the Roche Chemistrip 10SG & 2GP urine reagent test strips in use, were tested with the above expired control material. a. The laboratory did not record the urine control material lot numbers on the patient log sheet; therefore, surveyor could not determine the number of patient specimens tested with the pregnancy kit and urine test strips.
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 surveyor's review of the laboratory's QA policy and confirmed in an interview with the laboratory testing person, at this survey, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D5291 and D5417.