Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0901775	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Ob-Gyn Pllc	4850 Broad Rd, Ste 2c, Syracuse, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel competency records, standard operating procedures (SOPs), as well as interview with the Practice Manager (PM), the laboratory failed to document annual competency performance. FINDINGS: 1. There was no documentation of testing personnel (TP) annual competency performance since 2021. 2. This is contrary to instructions indicated in the current, approved SOPs. 3. The PM confirmed the findings on August 14, 2024, at approximately 2:00 P.M.
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 review of waived testing manufacturer's package insert instructions, lack of SOPs, laboratory area and storage room temperature records, as well as interview with

	the PM, the laboratory failed to monitor and document ambient room temperatures in the areas where waived test kits were stored and on-site laboratory testing was performed. FINDINGS: 1. There was no documentation of ambient room temperatures in the areas where waived test kits were stored and on-site laboratory testing was performed. 2. The BTNX, Inc. Rapid Response Fecal Immunochemical Test (FIT), Lot 2308015, Expiration: July 31, 2025; ProAdvantage by NDC Urine Pregnancy Cassette Device, Lot 0000644479, Expiration: November 21, 2024; and Pro Advantage Urine Reagent Strips, Lot URS 3060089, Expiration: September 12, 2025; manufacturer's package inserts included instructions for storage temperature ranges of 2 - 30 C. 3. The current, approved SOPs did not include instructions for monitoring and documenting ambient room temperatures in the laboratory area where waived test kits were stored and on-site laboratory testing was performed. 4. The PM confirmed the findings on August 14, 2024, at approximately 2:30 P.M.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of BD Affirm Microprobe Microprocessor analyzer quality assurance (QA) records, standard operating procedures, and interview with the PM, the laboratory failed to document Affirm positive and negative control reactivity on a weekly basis. FINDINGS: 1. There was no documentation of weekly Affirm positive and negative control reactivity for 2022 and 2023. 2. This is contrary to instructions included in the current, approved Equivalent Quality Control (EQC) SOP. 3. It was noted that monthly Affirm positive and negative control reactivity was performed and documented. 4. The PM confirmed the findings on August 14, 2024, at approximately 2:30 P.M.
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 review of BD Affirm Microprobe Microprocessor analyzer QA records, standard operating procedures, and interview with the PM, the Laboratory Director (LD) failed to comply with current, approved QA program to assure quality of laboratory services provided. Refer to D5471.

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 review of personnel competency performance records, SOPs, as well as interview with the PM, the LD failed to comply with current, approved policies to assure TP competency. Refer to D5209.