Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0167925	10/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Women's Ob/Gyn, Pc	401 Main St, 1st Fl, 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
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 review of the laboratory's standard operating procedures (SOPs), lack of thermometer calibration records, as well as interview with the office manager (OM), the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the Acu-Rite digital thermometer utilized for laboratory area room temperature and humidity monitoring where patient specimen processing and waived test storage occurred. 2. There was no calibration certificate documentation for the Fisher Scientific Digital Thermometer, SN: 122406714, utilized for Kenmore refrigerator/freezer temperature

	monitoring where BD Affirm VPIII analyzer control material storage occurred. It was noted that the respective digital thermometer included a calibration tag indicating recalibration due July 23, 2014. 3. The current, approved SOPs did not include instructions for thermometer calibration and calibration certificate retention. 4. The OM confirmed the findings on October 10, 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 specifications, lack of SOPs and temperature records, as well as interview with the OM, the laboratory failed to monitor and document temperatures in the areas where patient specimen processing and reagents, controls, and waived test kit storage occurred. FINDINGS: 1. There was no documentation of ambient room temperatures in the area where patient specimen processing and waived test kit storage occurred. 2. The McKesson Consult Diagnostics Fecal Occult Blood Tests, Lot: 0524231-2, Expiration: November 30, 2027; McKesson Consult Diagnostics hCG Combo Test Cassette, Lot: 0000852941, Expiration: March 6, 2026; and McKesson Consult Diagnostics 2GP Urine Reagent Strips, Lot: UR53070103, Expiration: September 13, 2025; manufacturer's package inserts included instructions for storage temperature ranges of 59 - 86F or 15 - 30C for the McKesson Consult Diagnostics Fecal Occult Blood Tests; and 36 - 86F or 2 - 30C for the McKesson Consult Diagnostics hCG Combo Test Cassettes and McKesson Consult Diagnostics 2GP Urine Reagent Strips. 3. There was no documentation of Kenmore refrigerator temperature monitoring where BD Affirm VPIII analyzer control material storage occurred. 4. BD Affirm VPIII analyzer control Microbiologics Tri-Valent Negative swabs, Lot: 24156201, Expiration: June 3, 2025; and Microbiologics Tri-Valent Positive swabs, Lot: 24169102, Expiration: June 16, 2025; manufacturer's package inserts included instructions for storage temperature ranges of 2 - 8C. 5. The current, approved SOPs did not include instructions for monitoring and documenting ambient room and refrigerator temperatures where patient specimen processing, waived test kit storage, and BD Affirm VPIII analyzer control material storage respectively occurred. 6. The OM confirmed the findings on October 10, 2024, at approximately 2:00 P.M.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on review of SOPs, patient specimen test records, as well as interview with the

	OM, the laboratory failed to document quality control results during patient testing. FINDINGS: 1. There was no documentation of BD Affirm VPIII Probe Analysis Card (PAC) internal control results recorded on the BD Affirm VPIII log sheets for each patient specimen batch run from July 28, 2022, through the current survey. For example: No PAC internal control results were documented for the following: December 5, 2022, to December 13, 2022, 48 patients; January 18, 2023, to January 19, 2023, 17 patients; April 27, 2023, to April 28, 2023, 17 patients. 2. The current, approved SOPs did not include instructions for documenting such activity. 3. The OM confirmed the findings on October 10, 2024, at approximately 2:00 P.M.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of SOPs, patient specimen test records, as well interview with the OM, the laboratory failed to document identity of Testing Personnel (TP) performing patient specimen testing. FINDINGS: 1. There was no documentation of TP identification recorded on the BD Affirm VPIII log sheets for each patient specimen batch run from July 28, 2022, through the current survey. 2. The current, approved SOPs did not include instructions for documenting such activity. 3. The OM confirmed the findings on October 10, 2024, at approximately 2:00 P.M.