Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2175509	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cathy J Berry Md Pc & Associates	101 Pine Street, 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
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 surveyor's review of Quality Control (QC) records, lack of validation /verification records for the two Beckman Dickinson (BD) Affirm VPN Microbial Identification Test system analyzers and an interview with the testing person, the laboratory failed to perform and document a complete method of verification /verification for the two BD Affirm VPN analyzers prior to patient testing on November 21, 2019. FINDINGS: The testing person confirmed that on March 11, 2020, at approximately 10:00 AM, that the laboratory failed to perform a verification for the two Affirm VPN analyzers when they were relocated from 101 Pine St. testing area to 109 Pine St. laboratory on November 21, 2019. a. the testing person confirmed that the laboratory failed to perform a verification for the two Affirm VPN analyzers when the analyzers were relocated from 109 Pine St. laboratory back to 101 Pine St. testing area on November 27, 2019. b. Approximately 500 patient specimens were tested and reported for Gardnerella vaginalis, Trichomonas vaginalis and Candida yeast from November 21, 2019 through survey date March 11, 2020.
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 the surveyor's review of the laboratory's Individual Quality Control Plan (IQCP), Quality Control (QC) records for the Affirm VPN test system and an interview with the testing person, the laboratory failed to follow the established Quality Control Plan (QCP) section of the IQCP for the Affirm VPN. FINDINGS: 1. The testing person confirmed on March 11, 2020 at approximately 10:30 AM, the laboratory failed to follow the established QCP section of the IQCP for the Affirm VPN, which states QC is performed weekly and with each new lot/shipment of PAC test cassettes using the Trivalent QC swab. 2. After reviewing the weekly QC & each new lot/shipment QC logs, the surveyor found that the two Affirm VPN analyzers were not labeled or defined as e.g. # 1 & #2; therefore, the surveyor could not determine if the testing person was following the established QCP for the Affirm VPN analyzers and performing QC for each new lot/shipment and weekly between the both analyzers from November 21, 2019 through survey date. 3.Approximately 500 patient specimens were tested and reported for Gardnerella vaginalis, Trichomonas vaginalis and Candida yeast from November 21, 2019 through survey date March 11, 2020.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on lack of validation/verification records for the two BD Affirm VPN analyzers and confirmed in an interview with the testing person, the laboratory director failed to ensure that validation/verification study was performed and documented for the two BD Affirm VPN analyzers prior to patient testing on November 21, 2019. Refer to D5421.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's IQCP, QC records for the Affirm VPN Test system and confirmed in an interview with the testing person, the laboratory director failed to follow the established QCP section of the IQCP for the Affirm VPN and failed to identify failures in the bacteriology, mycology and parasitology Quality Assessment (QA) program. Refer to: D5421 and D5445.