Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0948828	06/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
P & S Clinic Ob-Gyn Pllc	900 Earl Frye Blvd, Amory, MS	

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
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 the number of deficiencies cited for analytic systems, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 or monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289. Refer to D5411 (Failure to follow manufacturer's instructions for BD Affirm VPIII Microbial Identification Test). Refer to D5421 (Failure to verify performance specifications for BD Affirm VPIII Microbial Identification Test). Refer to D5449 (Failure to include a positive and negative control each day of BD Affirm VPIII Microbial Identification Testing).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on review of the manufacturer's instructions for Becton Dickinson (BD) Affirm VPIII Microbial Identification Test, observation of the BD MicroProbe Lysis Block in the laboratory on 6/15/2023 at 2:40 p.m., and lack of documentation of BD MicroProbe Lysis Block temperature and room temperature, the laboratory failed to monitor and document BD MicroProbe Lysis Block temperature and room temperature each day of patient testing with the BD Affirm VPIII Microbial Identification Test, to ensure testing was performed following manufacturer's instructions for 64 of 64 testing days, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. Findings include: 1. Review of the manufacturer's instructions for BD Affirm VPIII Microbial Identification Test revealed the Sample Preparation Procedure states, "Verify that the BD MicroProbe Lysis Block is at 85 degrees Celsius plus or minus 5 degrees Celsius and that reagents are at 22 to 28 degrees Celsius and well mixed." 2. Observation of the BD MicroProbe Lysis Block in the laboratory on 6/15/2023 at 2:40 p.m. revealed no thermometer inserted in the BD MicroProbe Lysis Block for monitoring the temperature. There was no documentation of the BD MicroProbe Lysis Block temperature for 64 of 64 testing days from 1/4/2023 through 6/1/2023, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. 3. Review of the temperature records for the room in which BD Affirm VPIII Microbial Identification Testing was performed revealed no documentation of room temperature for the 64 testing days from 1/4/2023 through 6/1 /2023, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species.
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 review of patient result logs for Becton Dickinson (BD) Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023 and lack of documentation of verification of performance specifications, to include accuracy and precision, the laboratory failed to verify performance specifications for the BD Affirm VPIII Microbial Identification Test before the test was put in use for patient Gardnerella vaginalis, Trichomonas vaginalis, and Candida species testing on 1/4 /2023. There was no documentation of verification of accuracy and precision for 64 of the 64 days of testing when 135 patient specimens were tested. Findings include: 1. Review of patient result logs for BD Affirm VPIII Microbial Identification Testing revealed the test was in use for 64 days from 1/4/2023 through 6/1/2023 with testing performed on 135 patient specimens. 2. There was no documentation of verification of performance specifications on 6/1/2023, to include accuracy and precision, for 64 of 64 days that the BD Affirm VPIII Microbial Identification Test was used to test for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species.
D5449	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient result logs for Becton Dickinson (BD) Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023, lack of documentation of performance of controls, and lack of establishment of an Individualized Quality Control Plan (IQCP), the laboratory failed to include a positive and negative control each day of patient testing for 64 of 64 days during this time frame, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species with the BD Affirm VPIII Microbial Identification Test. Findings include: 1. Review of patient result logs for BD Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023 revealed the test was in use for 64 days to test 135 patient specimens for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. 2. There was no documentation on 6/15 /2023 of performance of a positive and negative control for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species each day of patient testing for 64 of 64 days that the BD Affirm VPIII Microbial Identification Test was in use. 3. There was no documentation on 6/15/2023 of establishment of an Individualized Quality Control Plan (IQCP), required after 1/1/2016, if two levels of control are not included each day of patient testing.
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 number of deficiencies cited for analytic systems, technical consultant responsibilities, and laboratory director responsibilities, the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1407 of this subpart. Refer to D5400 (Condition of Analytic Systems). Refer to D6033 (Condition of Technical Consultant). Refer to D6013 (Failure to ensure verification of performance specifications for BD Affirm VPIII Microbial Identification Test). Refer to D6014 (Failure to ensure performance of test methods for accurate and reliable results). Refer to D6020 (Failure to ensure establishment of quality control program for BD Affirm VPIII Microbial Identification Test). Refer to D6029 (Failure to ensure testing personnel received appropriate training).
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 review of patient result logs for Becton Dickinson (BD) Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023 and lack of documentation of verification of performance specifications, to include accuracy and precision, the laboratory director failed to ensure verification procedures were performed to determine the accuracy and precision, and other pertinent performance characteristics, for the BD Affirm VPIII Microbial Identification Test before the test was put in use for patient Gardnerella vaginalis, Trichomonas vaginalis, and Candida species testing on 1/4/2023. The test was in use for 64 of 64 days from 1/4/2023 through 6/1/2023 with 135 patient specimens tested with no documentation of verification of accuracy and precision. Findings include: 1. Review of patient result logs for BD Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1 /2023 revealed the test was in use for 64 days from 1/4/2023 through 6/1/2023 with testing performed on 135 patient specimens. 2. There was no documentation of verification of performance specifications, to include accuracy and precision, for the BD Affirm VPIII Microbial Identification Test for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species for 64 of 64 testing days on 6/15/2023. Refer to D5421 (Failure to verify performance specifications for BD Affirm VPIII Microbial Identification Test).
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for Becton Dickinson (BD) Affirm VPIII Microbial Identification Test, observation of the BD MicroProbe Lysis Block in the laboratory on 6/15/2023 at 2:40 p.m., and lack of documentation of BD MicroProbe Lysis Block temperature and room temperature, the laboratory director failed to ensure laboratory personnel were performing BD Affirm VPIII Microbial Identification testing as required for accurate and reliable results when these individuals failed to monitor and document BD MicroProbe Lysis Block temperature and room temperature for 64 of 64 patient testing days when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. Findings include: 1. Review of the manufacturer's instructions for BD Affirm VPIII Microbial Identification Test revealed the Sample Preparation Procedure states, "Verify that the BD MicroProbe Lysis Block is at 85 degrees Celsius plus or minus 5 degrees Celsius and that reagents are at 22 to 28 degrees Celsius and well mixed." 2. Observation of the BD MicroProbe Lysis Block in the laboratory on 6/15/2023 at 2:40

	p.m. revealed no thermometer inserted in the BD MicroProbe Lysis Block for monitoring the temperature. There was no documentation of the BD MicroProbe Lysis Block temperature for 64 of 64 testing days from 1/4/2023 through 6/1/2023, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. 3. Review of the temperature records for the room in which BD Affirm VPIII Microbial Identification Testing was performed revealed no documentation of room temperature for 64 of 64 testing days from 1/4/2023 through 6/1/2023, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. Refer to D5411 (Failure to follow manufacturer's instructions for BD Affirm VPIII Microbial Identification Testing).
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of patient result logs for Becton Dickinson (BD) Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023, lack of documentation of performance of controls, and lack of establishment of an Individualized Quality Control Plan (IQCP), the laboratory director failed to ensure that a quality control program was established and maintained to assure the quality of laboratory services provided with the BD Affirm VPIII Microbial Identification Test for 64 of 64 days when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. Findings include: 1. Review of patient result logs for BD Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023 revealed the test was in use for 64 days from 1/4/2023 through 6/1/2023 with testing performed on 135 patient specimens for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. 2. There was no documentation on 6/15/2023 of performance of a positive and negative control, for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species, each day of patient testing for 64 of 64 days that the BD Affirm VPIII Microbial Identification Test was in use. 3. There was no documentation on 6/15/2023 of establishment of an Individualized Quality Control Plan (IQCP), required after 1/1/2016 if two levels of control are not included each day of patient testing. Refer to D5449 (Failure to include a positive and negative control each day of BD Affirm VPIII Microbial Identification Testing).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the

	type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory's personnel records, and interview with the compliance officer on 6/15/2023 at 11:30 a.m., the laboratory director failed to ensure that, prior to testing patients' specimens, Testing Personnel (TP) #2, #4, #12, #14, and #16 (5 of 11 TP) had received the appropriate training for moderate complexity testing and had demonstrated performance of all testing operations reliably to provide and report accurate results. Findings include: 1. Review of the CMS 209 personnel form and the laboratory's personnel records revealed the laboratory director failed to ensure that TP #2 and #4 received appropriate training for performing BD Affirm VPIII Microbial Identification testing, prior to testing patients' specimens, and failed to ensure Testing Personnel #12, #14, and #16 received appropriate training for performing complete blood count (CBC) testing with the CDS Medonic hematology analyzer, prior to testing patients' specimens. This was a total of 5 of 11 TP that did not have appropriate training. 2. In an interview on 6/15/2023 at 11:30 a.m., the compliance officer confirmed Testing Personnel #2 and #4 performed BD Affirm VPIII Microbial Identification testing and Testing Personnel #12, #14, and #16 performed CBC testing with the CDS Medonic hematology analyzer.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the number of deficiencies for technical consultant responsibilities and analytic systems, a qualified technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Refer to D5400 (Condition of Analytic Systems). Refer to D6040 (Failure to ensure verification of performance specifications for BD Affirm VPIII Microbial Identification Test). Refer to D6042 (Failure to establish quality control program for BD Affirm VPIII Microbial Identification Test). Refer to D6049 (Failure to review maintenance and quality control records for evaluation of competency of testing personnel).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of patient result logs for Becton Dickinson (BD) Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023 and lack of documentation of verification of performance specifications, to include accuracy and

	precision, a technical consultant failed to ensure verification of the BD Affirm VPIII Microbial Identification test procedures were performed, including accuracy and precision, before the test was put in use for patient Gardnerella vaginalis, Trichomonas vaginalis, and Candida species testing on 1/4/2023. There was no documentation of verification of accuracy and precision for 64 of 64 testing days from 1/4/2023 through 6/1/2023 with 135 patient specimens performed. Refer to D5421 (Failure to verify performance specifications for BD Affirm VPIII Microbial Identification Test).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of patient result logs for Becton Dickinson (BD) Affirm VPIII Microbial Identification Testing from 1/4/2023 through 6/1/2023, lack of documentation of performance of controls, and lack of establishment of an Individualized Quality Control Plan (IQCP), a technical consultant failed to establish a quality control program appropriate for the testing performed with the BD Affirm VPIII Microbial Identification Test for 64 of 64 testing days, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. Refer to D5449 (Failure to include a positive and negative control each day of BD Affirm VPIII Microbial Identification Testing).
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of CDS Medonic hematology analyzer preventive maintenance logs and quality control records from 1/6/2023 through 5/31/2023 and lack of documentation of review by a technical consultant, a technical consultant failed to document review of the CDS Medonic hematology analyzer preventive maintenance logs and quality control records, for evaluation of the competency of testing personnel, for five of five months, when a total of 359 patient complete blood count (CBC) tests were performed. Findings include: Review of the CDS Medonic hematology analyzer preventive maintenance logs and quality control records from 1/6 /2023 through 5/31/2023 revealed no documentation of review of these records by a technical consultant for five of five months, for evaluation of the competency of testing personnel, when a total of 359 patient CBC tests were performed.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5)

	Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for Becton Dickinson (BD) Affirm VPIII Microbial Identification Test, observation of the BD MicroProbe Lysis Block in the laboratory on 6/15/2023 at 2:40 p.m., and lack of documentation of BD MicroProbe Lysis Block temperature and room temperature, the testing personnel, responsible for BD Affirm VPIII Microbial Identification testing, failed to identify problems that could adversely affect test performance, when the room temperature and BD MicroProbe Lysis Block temperature were not monitored and documented for 64 of 64 testing days, when a total of 135 patient specimens were tested for Gardnerella vaginalis, Trichomonas vaginalis, and Candida species. Refer to D5411 (Failure to follow manufacturer's instructions for BD Affirm VPIII Microbial Identification testing).