Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D2145484	05/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Venus Ob-Gyn	1150 Reservoir Ave, Cranston, RI	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and staff interview, the laboratory director (LD) and testing personnel (TP) examining the proficiency samples failed to attest that proficiency testing (PT) samples were performed in the same manner as patient specimens. Findings Include: 1. Record review on 4/29/2022 of the American Association of Bioanalysts Vaginosis Screen Non Chemistry PT 2021 Quarter 3 and 2022 Quarter 1 attestation pages revealed, the attestation pages were not signed by the TP and LD. 2. Staff interview on 4/29/2022 at 10:40 AM with Office Manager and LD confirmed the above findings. 3. The laboratory performs 2,250 Microbiology tests annually.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during

	the PT event. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and staff interview, the laboratory failed to document and maintain a copy of proficiency testing (PT) records for a minimum of two years. Findings Include: 1. Record review on 4/29/2022 of the laboratory's American Association of Bioanalysts (AAB) 2021 Vaginosis Screen Non Chemistry Quarter 3 and 2022 Quarter 1 PT records revealed: a. Lack of documentation for the handling, preparation and processing of PT specimens. b. Lack of documentation for the examination and testing of PT specimens. c. Lack of documentation for the reporting of PT specimens to the PT Agency. d. The only records retained where the attestation sheets for PT mentioned in #1 above. e. The attestation sheets in #1 above were not signed by the Laboratory Director (LD) or Testing Personnel (TP). 2. Staff interview on 4/29/2022 at 10:40 AM with Office Manager and LD confirmed the above findings. 3. The laboratory performs 2,250 Microbiology tests annually.
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 surveyor observation, record review and staff interview, the laboratory failed to 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. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialty of Microbiology. Refer to D5407, D5413, D5415, D5421, D5453, D5791 and D5805.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to approve, sign, and date procedures before use. Findings Include: 1. Record review of The 'BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure' on 4 /29/2022 revealed the LD did not sign and approve the procedure. 2. Staff interview with the LD on 4/29/2022 at 10:10 AM confirmed the above findings. 3. Staff

	interview with the office manager on 4/29/2022 at 10:10 AM revealed the laboratory began patient testing in June of 2021 using the BD Affirm VPIII Microbial Identification Test. 4. The laboratory performs 2,250 Microbiology tests annually.
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 surveyor observation, lack of documentation, record review and staff interview, the laboratory failed to define criteria for for proper storage of reagents in the specialty of Microbiology. Findings include: 1. Record review on 4/29/2022 of the laboratory's refrigerator #1 (R1) temperature records revealed lack of documentation for temperature checks from 9/1/2021 through 1/31/2022. 2. Surveyor observation on 4 /29/2022 at 11:28 AM of the laboratory testing area revealed: a. A small refrigerator #2 (R2) containing the following: i. 14 BD Affirm VPIII proble analysis cards (PAC) lot # 1293078 exp. 12/25/2022. ii. 13 BD Affirm VPIII reagent cassettes lot # 1302251 exp. 10/25/2022 b. Both reagents in #2a above have a storage temperature requirement of 2 - 8 degrees Celsius. c. The R2 did not have a thermometer to record the temperature. d. The following reagents stored on the counter at room temperature: i. 1 container BD Affirm VPIII Buffer Solution lot # 1279679 exp. 9/29/2022. ii. 1 container BD Affirm VPIII Lysis Solution lot # 1046567 exp. 4/7/2022. iii. 1 container BD Affirm VPIII Substrate Solution lot #1132580 exp. 7/10/2022. e. Record review on 04/29/2022 of the BD Affirm VPIII Package insert states, "Alternatively, store at room temperature (up to 30 degrees Celsius) no more than 3 months." f. The laboratory did not have a thermometer to record the room temperature. 3. Staff interview with the office manager and testing personnel #1on 4/29/22 at 11:30 AM: a. Confirmed the temperature records referenced in #1 above were missing. b. Confirmed BD Affirm VPIII PAC and reagent cassettes are stored in R2 and daily temperature checks are not performed. c. Confirmed The 3 BD Affirm VPIII Solutions in d above are stored at room temperature and the room temperature is not recorded. 4. The laboratory performs 2,250 Microbiology tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory

	failed to label reagents with the new expiration dates after opening in the specialty of Microbiology. Findings include: 1. Surveyor observation of the laboratory on 4/29 /2022 at 11:28 AM revealed the following reagents stored at room temperature on the benchtop: a. One container BD Affirm VPIII Buffer Solution lot# 1279679 exp. 9/29 /2022. b. One container BD Affirm VPIII Lysis Solution lot# 1046567 exp. 4/7/2022. c. One container BD Affirm VPIII Substrate Solution lot # 1132580 exp. 7/10/2022. d. The above reagents did not have an open date or new expiration date recorded on the bottle. 2. Record review on 04/29/2022 of the BD Affirm VPIII Package insert states, "Alternatively, store at room temperature (up to 30 degrees Celsius) no more than 3 months." 3. Staff interview with the office manager (OM) and testing personnel #1 (TP1) on 4/29/2022 at 11:30 AM confirmed the above reagents are stored at room temperature and not labeled with the new expiration date after opening. The OM stated OM was not aware of the change in expiration date for the BD Affirm reagents once they are opened and stored at room temperature. TP1 stated TP1 changes the reagents every 2 weeks and that is why the new expiration date is not documented. 4. The laboratory performs 2,250 Microbiology tests annually.
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 lack of documentation, record review and staff interview the laboratory failed to validate performance specifications for a new analyzer prior to reporting patient test results in the specialty of Microbiology. Findings include: 1. Record review on 4/29/2022 of the laboratory 's validation data for the BD Affirm VPIII revealed: a. The only record on file was a package insert from Gibson BioScience entitled, 'Certificate of Analysis VV-01 Vaginitis Validation Panel '. This sheet contained the expected results of 22 test swabs for Gardnerella, Trichomonas and Candida. b. The laboratory did not have documentation that it ran any of the above test swabs on the BD Affirm to establish that it can obtain the same results before performing testing on patients. c. the laboratory did not have any documentation that it performed any validation studies to establish that it can obtain the same results before performing testing on patients. 2. Staff interview with the office manager (OM) and Testing Personnel #1 (TP1) on 4/29/2022 at 11:50 AM confirmed: a. Patient testing using the BD Affirm for Trichomonas, Yeast and Gardnerella testing went live in June of 2021. b. The laboratory did not have any validation documentation for the BD Affirm for the above tests. c. TP1 and the OM stated a technical representative from the instrument manufacturer performed the validation, but did not leave documentation with the laboratory. d. OM was unable to contact the manufacturer to obtain the validation data. 3. Record review on 5/5/2022 of an email received from the OM on 5/5/2020 at 2:15 PM revealed: a. The same attachment as in 1a above. b. "I contacted the manufacturer and this is the only document that they sent me. It is the

	same sheet that we have. They said that this self reported and once we have the same results, we don't send them to the manufacturer back." 4. . The laboratory performs 2,250 Microbiology tests annually.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(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 test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to perform daily external quality control to detect errors in the extraction phase when performing the BD Affirm VPIII test assay in the specialty of Microbiology. Findings include: 1. The laboratory provided no documentation for running external quality control material since testing on the BD Affirm began in June of 2021. 2. Staff interview on 4 /29/2022 at 10:37 AM with testing personnel #1 confirmed the above finding. TP1 stated, "After I write down the controls on my notepad, I throw the notes away." 3. The laboratory performs 2,250 Microbiology tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to have a written quality assurance procedure in the specialty of Microbiology. Findings include: 1. The laboratory did not have a written procedure for analytic systems quality assessment (QA). 2. The laboratory provided no documentation for monitoring the quality of Microbiology analytic systems. 3. Staff interview with the office manager on 4/29/2022 at 10:10 AM confirmed the laboratory did not have a procedure for analytic systems QA and QA was not performed. 4. The laboratory performs 2,250 Microbiology tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to indicate the name and address of the laboratory location where the test was performed on the final patient test report in the specialty of Microbiology. Findings include: 1. Record review of a patient final report on 4/29/2022 revealed the name and address of the laboratory performing patient testing was not on the report. 2. Staff interview with the office manager on 4/29/2022 at 11:30 AM confirmed the name and address of the laboratory where testing was performed was not on the final patient test report. 3. Laboratory performs approximately 2,250 tests annually in the specialty of Microbiology.
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 lack od documentation, surveyor observation, record review and staff interview, the laboratory director failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the specialty of microbiology. Refer to D6013, D6014, D6016, D6019, D6022, D6030 and D6031.
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: Refer to D5421
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 lack of documentation, record review and staff interview, the laboratory director (LD) failed to assess testing personnel (TP) competency for their roles and responsibilities to ensure accurate and reliable patient testing and result reporting. Findings include: 1. Record review on 4/29/2022 of the laboratory's employee records revealed the laboratory did not document the assessment of employee competency to perform moderate complexity testing in the specialty of microbiology since the laboratory began testing on the BD Affirm in June of 2021. 2. Staff interview with the office manager on 4/29/22 at 10:25 AM confirmed the above finding. 3. The laboratory performs 2,250 Microbiology tests annually.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Refer to D2009 and D2015.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to investigate or take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review on 4/29/2022 of 'CMS CASPER 0155D Individual Laboratory Profile Report,' revealed a score of 80% for 2021 PT Event 3 for the regulated analyte 0005 bacteriology. 2. Investigation or remedial action was not documented for the above PT event. 3. Staff interview with the office manager (OM) and the LD on 4/29/2022 at 10:40 AM confirmed the PT score of 80% was not investigated and remedial action was not taken to correct the PT error. 4. The laboratory performs 2,250 Microbiology tests annually.
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: Refer to D5453 and D5791.
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 lack of documentation, record review and staff interview, the laboratory director (LD) failed to establish policies and procedures to assess the competency of moderate complexity testing personnel. Findings include: 1. Record review on 4/29 /2022 of the laboratory's procedure manual revealed the laboratory did not have a procedure to assess the competency of moderate complexity testing personnel. 2. Staff interview with the office manager on 4/29/2022 at 10:25 AM confirmed the above finding. 3. The laboratory performs 2,250 Microbiology tests annually.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Refer to D5407.