

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D2145484	(X3) Date Survey Completed 12/14/2023
Name of Provider or Supplier Venus Ob-Gyn	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, record review and staff interview, the laboratory failed to maintain copies of signed attestation statements for 3 of 4 proficiency testing (PT) events in the specialty of Microbiology. Findings include: 1. Record review on 12/07/2023 of the laboratory's 2023 American Association of Bioanalysts Vaginosis Screen Non Chemistry PT documentation revealed the laboratory did not have signed attestation sheets for Events 1, 2 and 3. 2. Staff interview on 12/07/2023 at 10:00 AM with the Office Manager (OM) confirmed the above findings. The OM stated, "They do not send us attestation sheets anymore. I enter the results electronically. We do not have the analyst sign anything." 3. The laboratory performs 2,400 Microbiology tests annually.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 12/07/2023 of the laboratory's "New Laboratory Employees Training and Competency Requirements" procedure revealed: a. "At 6-months, the new employee will be given a Competency Assessment." b. "Upon the completion of the new employees first year, an annual Competency Assessment will be performed and then annually thereafter." 2. Record review on 12/07/2023 of the laboratory's Testing Personnel (TP) competency documentation for the BD Affirm VPIII revealed: a. TP1 had an initial competency assessment on 06/06/2022. b. TP2 had an initial competency assessment on 06/08/2022. c. A second competency assessment was not documented within the first year for TP1 and TP2. 3. Staff interview on 12/07/2023 at 9:35 AM with the Office Manager (OM) confirmed the above findings. The OM stated, "We were not aware they needed to do 2 in the first year." 4. The laboratory performs 2,400 Microbiology tests annually. *This is a repeat violation.*

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 lack of documentation, record review and staff interview, the laboratory director failed to ensure training was documented for 2 of 2 new testing personnel (TP) in 2022 for the BD Affirm VPIII. Findings include: 1. Record review on 12/07/2023 of the laboratory's "New Laboratory Employees Training and Competency Requirements" procedure revealed, "A training record will be completed and signed off by the lab director to ensure an employee is ready to work independently." 2. Record review on 12/07/2023 of the laboratory's 2023 CMS-209 form compared with the 2022 CMS-209 form revealed 2 new TP. 3. Record review on 12/07/2023 of the laboratory's TP records revealed: a. TP1 began patient testing using the BD Affirm VPIII on 06/06/2022. b. TP2 began patient testing using the BD Affirm VPIII on 06/08/2022. c. A lack of documentation for training on the BD Affirm VPIII for the 2 new TP noted in 3a and 3b above. 4. Staff interview on 12/07/2023 at 9:28 AM with the

Office Manager (OM) confirmed that training was not documented for 2 of 2 new testing personnel in 2022. The OM stated, "They were trained, but we did not document it." 5. The laboratory performs 2,400 Microbiology tests annually.