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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D0936307    | <b>(X3) Date Survey Completed</b><br><br>08/26/2024 |
| <b>Name of Provider or Supplier</b><br><br>West Valley Women's Health  | <b>Street Address, City, State</b><br><br>777 Knowles Dr Ste 7, Los Gatos, CA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D2000</b>              | <p>ENROLLMENT AND TESTING OF SAMPLES<br/>CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on observation of the BD Affirm VPIII analyzer for Gardnerella, Candida, and Trichomonas; review of proficiency testing reports from CMS/CLIA (report 155D, Individual Laboratory Profile) and AAFP (American Academy of Family Physicians) and laboratory tests records, the lack of proficiency testing records, and interviews with Testing person-1 and the Laboratory Director, it was determined that the laboratory failed to enroll in proficiency testing in 2023 and 2024. Findings included:<br/>1. CMS and AAFP reported proficiency testing scores for 2022, but none for 2023 and 2024. 2. The laboratory failed to have records for proficiency testing in 2023 and 2024. 3. Laboratory "QC Evaluation Logs" recorded testing of external control Trivalent Swab in 2023- 2024, as follows: 2023 2024 ----- 4/17/23 1/15 /24 6/14/23 3/14/24 8/01/23 5/24/24 9/28/23 11/30/23 4. The laboratory's "Patient Test Log" documented testing in 2023 and 2024, including the following selected for this survey: Date ID Kit Lot # Tests Results<br/>----- 12/18/23 LC 3235665 Neg 1/03/24<br/>MK 3235665 Pos for Gardnerella 2/01/24 LC 3212047 Neg 4/30/24 OZ 3310323 Pos for Gardnerella 5/14/24 DT 3310323 Pos for Gardnerella and Candida 8/23/24 WX 4023432 Neg 8/26/24 MS 4023432 Pos for Gardnerella 5. Testing Person-1 confirmed</p> |

(8/26/24 at 3:30 PM) the aforementioned findings, that the laboratory had tested Trivalent Swabs and patients specimen for Affirm continuously from 2022 to present 2024, but had not enrolled in proficiency testing in 2023 and 2024. 6. The Laboratory Director confirmed that patients specimen had been tested for Affirm continuously from 2022 to present 2024, but without proficiency testing in 2023 and 2024. 7. A laboratory may test patients specimen on the condition that it enrolls and participates in proficiency testing. However, the laboratory failed to comply with this requirement; and thus the reliability and quality of Affirm test results reported in 2023 - 2024 could not be assured. a. The laboratory tested 300 specimens annually and thus reported 1,200 tests results (CMS116 CLIA Application, 8/26/24). i. Seven records were selected for the Laboratory Director/Clinical Consultant's quality assessment review, as mentioned above (see statement 4) ii. The laboratory tested other patients specimen in 2023, that are not mentioned in this survey report and require quality assessment review as well. .

**D3031**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:  
Based on review of laboratory "QC Evaluation Log" records, the lack of "Patient Test Log" records for the timeframe 2021 to December 2023, and interview with Testing Person-1, it was determined that the laboratory failed to retain patient test records for at least two years from date of testing. Findings included: a. The State Business and Professions Code (BPC) 1265(J)(2)(A) requires laboratory records to be retained 3 years from date of testing unless a longer retention time is required: (2)(A) Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department. b. Laboratory "QC Evaluation Log" records documented testing external QC Trivalent Swab for the timeframe 1/5/21 through 11/30/23. c. The laboratory documented Affirm test results on it's "Patient Test Log" records, but failed to have records for the timeframe Jan. 2021 through December 17, 2023. d. Testing Person-1 confirmed (8/26/24 at 2:00 PM) that the Affirm test had been continuously in use prior to January 2021, and that the patients' test records for 2021 to 2023 had been discarded. e. The reliability and quality of Affirm results reported for the timeframe January 2021 to December 2023 could not be assured in this CLIA survey. .

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on the Condition level deficiency cited (D2000), the Laboratory Director is herein cited for deficient practice in ensuring the laboratory is enrolled in proficiency testing when testing patients specimen. .