

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0931296	<b>(X3) Date Survey Completed</b>  06/13/2024
<b>Name of Provider or Supplier</b>  Vasanth Vishwanath Md Inc	<b>Street Address, City, State</b>  7075 N Maple Ave Ste 102, Fresno, 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>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures for all the tests performed in the laboratory and interviews with the laboratory personnel (LP); it was determined that the laboratory failed to have available written procedures at the time of the survey. The findings included: 1. On the day of the survey on June 13, 2024, at approximately 3:30 p.m., the laboratory failed to provide written policies and procedures for all the tests performed in the laboratory including the proficiency testing policy and procedure. 2. For five (5) out of (5) randomly selected patient test results reviewed for tests performed in the lab, no Standard Operating Procedures</p>

(SOP) were available at the time of survey that followed the regulated format. 3. The LP confirmed on 06/13/2024 at approximately 3:45 p.m. that the laboratory did not have written policies and procedures available for all testing performed.

**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 the incomplete laboratory's verification of performance characteristics for moderate complexity testing for Bacterial Vaginosis (BV), Neisseria gonorrhea & Chlamydia trachomatis (GC/CT), Candida species, and Trichomonas vaginalis (TV) identification by nucleic acid amplification test (NAAT), interviews with the testing person (TP) and office manager (OM), and review of five (5) randomly selected patient test records; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had documentation to show for the testing of 24 samples for BV, GC/CT, TV, and Candida spp. using the BD Max instrument when the instrument was acquired. However, data was lacking calculation of performance characteristic (indicated below) and documentation. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics and those to be approved by the laboratory director before starting testing patients' samples: (A) Accuracy (B) Precision (C) Reportable range (D) Reference Range 2. The laboratory was unable to provide for review additional documents using patient samples to establish performance specification for BV, GC/CT, TV, and Candida species. 3. The TP and OM affirmed at the time of the survey on 06/13, 2024 at approximately 2:45 p.m. that no additional documents could be retrieved to show that performance specification were performed prior to reporting patient test results when the laboratory went live testing and reporting BV, GC/CT, TV, and Candida species diagnostic tests. 4. Based on the estimated annual tests volumes signed by the laboratory director on 06/11/2024; the laboratory performed and reported approximately 17,800 diagnostic tests which included BV, GC/CT, TV, and Candida species The precision and accuracy of the reported tests results could not be assured.

**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 review of the final test reports for five (5) patients randomly selected and interview with laboratory personnel (LP), it was determined that the laboratory failed to state the complete name of the analytes tested, reference, and the name of the person releasing the results. Findings included: 1. In addition to this CLIA requirement, the California Business & Professions Code (BPC) 1288 requires " A report of results issuing from a clinical laboratory shall show clearly the name and address of the laboratory and the name of the director". 2. LP affirmed on the day of the survey, 06/13/2024 at approximately 3:30 p.m., the aforementioned findings. 3. The laboratory stated a combined total of 17,800 urogenital samples tested and reported annually.

**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 the deficiency cited (D5421), the laboratory director is herein cited for deficient practice in ensuring test system verification procedures were compliant with the regulations at 493.1253(b)(1) before the laboratory personnel was allowed to test patients' samples without confirming the manufacturer's performance specifications.

**D6026**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of the laboratory result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that reports of test results include the name of the test and pertinent information required for interpretation. The findings included: see D-5805.