Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0931296	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Vasanth Vishwanath Md Inc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 observation, lack of temperature logs and interview with the testing personnel (TP), it was determined that the laboratory failed to monitor and document temperatures. The findings included: 1. On the day of the survey, 01/12/2021 based on observation and interview with the testing personnel, the laboratory failed to provide documentation for the temperatures for 2019, 2020 and 2021 in which patient testing had been performed. The BD Max analyzer system manufacturer's guidelines, "States that the BD Max system must perform within ranges of 2 C and 25 C degrees". This included the monitoring of the analyzer system as well as the reagents to determine if the temperature had exceeded manufacture's guidelines for operation and storage. 2. The testing personnel confirmed on 12/4/2019, 12:00 a.m. that the laboratory has no temperature (logs) documentation for 2019, 2020 and 2021.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified

	in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC) and Trichomonas vaginalis (TV) and the vaginal panel (Bacterial vaginosis, Candida sp. and TV) moderate complexity testing platforms performed on the BD MAX system analyzer, interviews with the laboratory testing personnel on 10/12/2021 (survey date) and ten (10) randomly selected patient testing results from 01/19/2019 to 09/25/2020, it was determined that the laboratory failed to perform control procedures as defined per manufacturer's guidelines, or CLIA regulation 493.1256 (d) (2) "For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in" (d)(3) "At least once each day patient specimens are assayed or examined perform the following for:" (whichever is more stringent). The laboratory also had not instituted an alternate "Individual Quality Control Plan" (IQCP) including Risk Assessment, Quality Control and Quality Assessment. The findings included: 1. The laboratory performed CT, GC and TV and vaginal panel (Bacterial vaginosis, Candida sp. and TV) moderate complexity testing on the BD MAX system analyzer . The manufacturer's guidelines under "Quality Control Procedures" 2.) It is recommended that one (1) External Positive control and one (1) External Negative Control be run at least daily until adequate process validation is achieved on the BD MAX system in each laboratory setting. Reduced frequency of control testing should be in accordance with applicable regulations." The laboratory since the introduction of the BD MAX system had performed external quality controls approximately once every 30 day, yet no written IQCP policy was in place. The external quality controls run relative to 09 /25/2020 had exceed 30 days yet patient testing(s) was being resulted and reported. 09 /25/2020 Patient Accession # 1033505 - Quality control exceeded 30 days. 2. The laboratory testing personnel affirmed on 01/12/2021, 12:00 a.m. (survey date) that QC was not performed in accordance with manufacturer's guidelines, or CLIA regulation 493.1256 (d) (2), (d) (3) and that no alternative IQCP program was instituted for the BS MAX system for all testing performed and reported and that during the period of 09/25/2020 that patient testing results were reported even though no quality controls were run for a period that had exceeded 30 days. 3. The annual laboratory testing declaration signed on 01/12/2021 stated that the laboratory performed approximately 5,600 BD MAX tests for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC) and Trichomonas vaginalis (TV) vaginal panel (Bacterial vaginosis, Candida sp. and TV).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:

	Based on review and the lack of documentation for competency assessments, and interview with a laboratory personnel, it was determined that the laboratory technical consultant (laboratory director) failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: 1. No documentation could be retrieved to show that the testing personnel were evaluated during the first six months for their responsibilities as testing personnel and annually thereafter. The evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem-solving skills 2. The laboratory personnel affirmed 01/12/2021 at 12:00 a.m. (survey date) that no semiannual competency assessment and annual competency evaluations was performed and documented by the technical consultant (laboratory director) on the testing personnel performing moderate complexity testing in 2019 and 2020.