Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0713674	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gopal Reddy Gade Md	6183 N Fresno St Ste 105, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition for General Laboratory Systems was not met. The laboratory failed to follow the written laboratory policy and procedure to assess employee competency (See D6030); failed to evaluate and document the performance of an individual(s) responsible for moderate complexity testing at least semiannually during the first year the individual (s) tests patients, and thereafter, evaluations must be performed at least annually (See D6053, D6054). The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems (See D5891).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on review of patient testing log, patient final testing reports [electronic medical records (EMR)], and interview with the laboratory personnel, it was determined that from 03/26/2019 through 07/10/2020 for one (1) out of ten (10) random patient testing records reviewed, the laboratory failed to follow written policies and procedures for specimen collection, through completion of testing and reporting results. The findings included: 1. Review of the AFFIRM VPIII Microbial Identification (AFFIRM) patient test logs on 09/10/2020 at 11 a.m. (survey date) and patient medical record (MR), it was found that patient test results were not reported (scanned) in the patient's medical record. On 07/10/202 review of the AFFIRM testing log showed patient ID M M receipt time of 9:54 [Trichomonas vaginalis (-), Gardnerella vaginalis (+) and Candida sp. (-)] were resulted in the patient test log, but could not be retrieved in the patient's electronic medical record (EMR). 2. On 09/10//2020 at 12:30 a.m. (survey date), the laboratory personnel affirmed that the patient testing results could not retrieve in the patient medical records. 3. Based on the laboratory's annual test volume declaration 08 /30/2019 (last test volume submitted) the laboratory performed 10,000 AFFIRM VPII patient microbial identification tests.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review of the laboratory's AFFIRM VPII microbial testing records and interview with the laboratory personnel on 09/10/2020, the laboratory failed to establish and maintain the accuracy of its testing procedures, in accordance with 493. 1236(c)(1), "to at least twice annually verify the accuracy of any test or procedure it performs that is not included in subpart I". The findings included: 1. The laboratory was enrolled in the American Academy of Family Physicians (AAFP) proficiency testing for AFFIRM VPIII (G. vaginalis, Candida sp., T. vaginalis) for events 2020-A and 2020-B, the laboratory failed to verify the accuracy of the tests performed by nonparticipation in both consecutive events of 2020. 2. The laboratory personnel affirmed by interview on 09/10/2020 at 12:30 a.m. that the laboratory failure to perform and document twice annual verification for the AFFIRM VPII (G. vaginalis, Candida sp. and T. vaginalis) testing 3. Based on the laboratory's annual test volume declaration 08/30/2019 (last test volume submitted) the laboratory performed 10,000 AFFIRM VPII patient microbial identification tests.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy & procedure, patient test record review from 03/26/2019 to 07/10/2020 for 10 randomly selected patients, and interview with the laboratory personnel on 09/10/2020, at 12:30 a.m. it was

	determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings included: 1. No written policies and procedures for postanalytic system quality assessment reviews could be retrieve. (See D5203).
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the 2020-A and 2020-B American Academy of Family Physicians (AAFP) proficiency events of the AFFIRM VPIII testing records, random patient test results and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that results are returned within the timeframes established by the proficiency testing program. (See D 5217).
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 the lack of laboratory personnel competency evaluation, the lack of laboratory written policies and procedures for assessing individual performances and interview with the testing person, the laboratory director failed to 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. (See D6053, D6054).
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: a. No documentation could be retrieved to show that the new testing personnel was evaluated during the first six months (2020) for their responsibilities as testing personnel. 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 1. The laboratory personnel affirmed 09/10/2020 at 12:30 a.m. (survey date) that no semiannual competency assessment was performed and documented by the technical consultant (laboratory director) on the new testing personnel performing moderate complexity testing in 2020.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for competency assessments, and interview with the 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 at least annually. The evaluations must include but are not limited to the following: a. No documentation could be retrieved to show that the testing personnel was evaluated at least annually the responsibilities as testing personnel. 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 1. The laboratory testing personnel confirmed 09/10/2020 (survey date) 12:30 a.m. that no competency assessment could be retrieved evaluating and documenting the performance by the technical consultant (laboratory director) of the testing personnel responsible for moderate complexity testing for 2018 and 2019.