Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2044711	08/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vitality Center Of Charlotte	300 Billingsly Road Suite 204, Charlotte, NC	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of 2020, 2021, 2022 and 2023 API (American Proficiency Institute) proficiency testing records and interview with TP (Testing Personnel) #1 on 8/1/23, the laboratory failed to include all testing personnel in the performance of proficiency testing events. Finding include: Review of 2020, 2021, 2022 and 2023 API proficiency testing records revealed that TP #1 performed all 11 of 11 proficiency testing events received by the laboratory. TP #1 signed all attestation statements in the years 2020, 2021 and 2022. An interview with TP #1 at approximately 10:05 a.m. confirmed that other testing personnel did not participate in proficiency testing events.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, 2022 and 2023 API proficiency testing records, review of the laboratory's policies and procedures, and interview with TP #1 on 8/1 /23, the laboratory failed to sign and maintain attestation statements for 2 of 2 proficiency testing events in 2023. Findings include: Review of 2020, 2021, 2022 and

	2023 API proficiency testing records revealed the absence of signed attestation statements for the First and Second Chemistry events of 2023. Review of the laboratory's "Tab 3: Proficiency Testing Policies" states "Carefully complete all PT forms...have the Lab Director sign the Attestation statement..." An interview with TP #1 at approximately 10:05 a.m. confirmed the laboratory did not sign and retain attestation statements for proficiency testing events performed in 2023.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, 2022 and 2023 API proficiency testing records, review of the laboratory's policies and procedures, and interview with TP #1 on 8/1 /23, the laboratory failed to perform corrective actions when an unsatisfactory score was received during the First Chemistry Proficiency Testing Event of 2023. Findings include: Review of the laboratory's 2020, 2021, 2022 and 2023 API proficiency testing records revealed a score of 50% for testosterone during the First Chemistry Event of 2023. The laboratory reported an unacceptable testosterone result for specimen IA-02. Review of the laboratory's "Tab 3: Proficiency Testing Policies, Section: Procedure for Proficiency Testing Failure" states "If your laboratory receives a failing score on an individual PT event, take action to identify and correct the problem." An interview with TP #1 at approximately 10:05 a.m. revealed she was unaware corrective actions needed to be documented for this unsatisfactory score.
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 review of the laboratory's records to verify the performance specifications of the Qualigen instrument and interview with TP #1 on 8/1/23, the laboratory failed to properly assess the precision of its new Qualigen instrument by determining day-to-day variance, as well as operator variance. Findings include: Review of the laboratory's records to verify the performance specifications of its Qualigen instrument revealed all activities to assess precision were performed on the same day, 11/30/22, by the same operator, TP #1. An interview with TP #1 at approximately 11: 10 a.m. confirmed the findings.
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 review of personnel records, review of the laboratory's policies and procedures, and interview with TP #1 on 8/1/23, the Laboratory Director failed to perform a competency evaluation on TP #2. Findings include: A review of personnel competency records revealed the absence of a documented competency for TP #2 in the years 2020, 2021, 2022 and 2023. A review of the laboratory's policy "Tab 4: Testing Personnel, Section: Laboratory Personnel Policies" states "...testing personnel are periodically evaluated to ensure that competency is maintained over time." Also, policy "Tab 4: Testing Personnel, Section: Laboratory Director Responsibilities" states "The Laboratory Director Confirms the Following: ...Personnel have been checked to assure their competence prior to reporting results. Policies and procedures exist to monitor testing personnel and identify needs for remedial training and/or continuing education." An interview with TP #1 at approximately 9:45 a.m. revealed that the competency of TP #2 had not been assessed.