Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2044711	09/25/2019
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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 Qualigen FastPack Testosterone QC (Quality Control) records, review of the laboratory's Risk Assessment and IQCP (Individualized Quality Control Plan), and review of patient logs 9/25/19, the laboratory failed to ensure the results of QC testing were acceptable before reporting patient results. Findings: The laboratory's risk assessment and IQCP for the Qualigen FastPack Testosterone Test states on page 3 "...CONTROLS OUT of RANGE Patient testing should not be performed if external Quality Controls are out of range for that product. This error could have high impact..." Review of the FastPack Testosterone QC records revealed Control Level 1 was outside of the QC acceptable range on 12 days from 12/15/17 through 12/13/18. Daily QC was performed as part of the risk assessment until 3/16/18, when the laboratory began performing QC weekly based on the IQCP. Approximately 177 patients were tested during the time frames when Control level 1 was unacceptable. The dates, results and number of patients are as follows: Control Level 1 (C1) lot # 1704036 (acceptable range:110-310 nanogram per deciliter(ng/dL) tested on the following: 1. 12/15/17: C1 result 706 ng/dL -2 patients; 2. 1/9/18: C1 result 314 ng/dL- 4 patients; 3. 5/24/18: C1 result 364 ng/dL- 22 patients between last acceptable QC run 5/17/18 to 5/29/18; 4. 7/25/18: C1 result 315 ng/dL - 34 patients between last acceptable QC run 7/19/18 to 8/2/18; 5. 9/6/18: C1 result 333 ng/dL; 6. 9/12/18: C1 result 519 ng/dL; 7 9/20/18: C1 result 319 ng/dL - 39 patients between last acceptable QC run 8/30/18 to 9/27/18; 8. 10/25/18: C1 result 321 ng/dL -30 patients between last acceptable QC run 10/18/19 to 11/1/18; 9. 11/26/18: C1 result 479 ng/dL; 10. 11/29/18: C1 result 603 ng/dL; 11. 12/6/18: C1 result 475 ng/dL;

	12. 12/13/18: C1 result 599 ng/dL -46 patients between last acceptable QC run 11/15 /18 to 12/20/18.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Risk Assessment and IQCP (Individualized Quality Control Plan) for the Qualigen FastPack testosterone test, review of the laboratory's monthly Quality Assurance Assessment records (QA) 9/25/19, and the deficiency cited at D5481, the laboratory failed to take and document corrective action when QC(Quality Control) was outside of acceptable range. Findings: The laboratory's risk assessment and IQCP for the Qualigen FastPack testosterone test states on page 3 "... CONTROLS OUT OF RANGE Describe what action would be taken if testing was mistakenly performed using product that had failed external QC (either Control 1 or Control 2 running out of range) Going back to time point of the previous passing external QC event, FastPack results would not be reported, and those patient samples would be sent out for retesting at outside lab. Patient testing would resume upon resolution of the external QC issue..." Review of monthly QA records revealed no corrective action was documented when the FastPack Testosterone Control Level 1 was outside of the acceptable range. (See D5481)