Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2237074	05/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Spartan Medical Men's Health Clinic	9145 Narcoossee Road Suite A102, Orlando, FL	

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
D0000	An initial certification survey was conducted on May 6, 2022. Spartan Medical Men's Health Clinic laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the initial competency assessment for one of one Technical Consultant from 10/25/2021 to 05/06/2022. Findings: Review of the Laboratory Personnel Report dated and signed by the Laboratory Director on 04/18/2022 showed there was one Technical Consultant. Review of the binder with patient test results showed patient testing started 10/25/2021. Review of personnel records revealed there was no initial competency evaluations for the Technical Consultant. On 05/06/2022 at 11:14 AM, Testing Personnel A stated there was no competency evaluation for the Technical Consultant.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on record review, observation, and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and identify problems. Findings: Cross Reference D5445. Based on record review, observation, and interview, the laboratory failed to follow their IQCP (Individualized Quality Control Plan) to run weekly (7 days) quality controls (QC) on the Qualigen FastPack IP System before reporting patient test results from 12/06/2021 to 05/06/2022.
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 record review, observation, and interview, the laboratory failed to follow their IQCP (Individualized Quality Control Plan) to run weekly (7 days) quality controls (QC) on the Qualigen FastPack IP System before reporting patient test results from 12/06/2021 to 05/06/2022 Findings: According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 04/18/2022, the laboratory performed testing on serum for PSA (Prostate-Specific Antigen) and Testosterone. The laboratory had an annual test volume of 9,000 tests. Review of the laboratory's IQCP showed that "For all FastPack tests, Controls 1 and 2 will be performed at least once per week and after calibration." The procedure also noted, "run QC before testing patients once per week on the same day." Review of the QC logs for PSA showed one patient was tested before the controls (C1, C2) were run on the following dates: 12/06/2021 1 patient tested at 11: 50 AM C1 run at 1:02 PM C2 run at 1:15 PM 02/02/2022 1 patient tested at 10:49 AM C1 run at 3:17 PM C2 ran at 3:31 PM Review of the QC logs for PSA showed controls were run on 02/02/2022 and then not again until 03/17/2022. Review of patient logs showed patients were tested on the following dates: 02/11/2022 - 1 patient 02/16/2022 - 1 patient Review of the QC logs for PSA showed controls were run on 03 /28/2022 and then not again until 04/19/2022. Review of the patient logs showed patients were tested on the following dates: 04/04/2022 - 2 patients 04/06/2022 - 1 patient 04/11/2022 - 3 patients 04/15/2022 - 1 patient Review of the QC logs for PSA showed the controls were run on 04/26/2022 and were not run as of the time of the survey on 05/06/2022. Review of the patient logs showed patients were tested on the following dates: 05/02/2022 - 2 patients 05/05/2022 - 1 patient Review of the QC logs for PSA showed the controls were run on 04/26/2022 and were not run as of the time of the survey on 05/06/2022. On 05/06/2022 at 11:30 AM, the Qualigen FastPack PSA test kit for two patients were observed on the counter with test results reported on the label with the patients' names. Review of the QC logs for Testosterone showed the controls were run on 03/13/2022 and then not again until 04/05/2022. Review of

	the patient logs showed patients were tested on the following dates: 03/28/2022 - 4 patients 03/29/2022 - 2 patients 03/30/2022 - 2 patients 04/01/2022 - 2 patients 04/02 /2022 - 1 patient 04/04/2022 - 2 patients Review of the QC logs for Testosterone showed the controls were run on 04/18/2022 and then not again until 04/26/2022 (day 8). Review of the patient logs showed one patient was tested on 04/25/2022. On 05/06 /2022 at 11:15 AM, Testing Personnel A stated they did not run controls some of the times because they ran out.
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 record review and interview, the laboratory failed to include name and address of the laboratory, and the normal values for three of three patients' laboratory test reports, (#1, #2, #3). Findings: Review of patients' test reports with the "In-House Labs" showed the name and address of the laboratory, and the normal values were not listed on the reports. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 04/18/2022, the laboratory performed testing on serum for PSA (Prostate-Specific Antigen) and Testosterone, and had an annual test volume of 9,000 tests. On 05/06 /2022 at 12:25 PM, Testing Personnel A confirmed the report with "In-House Labs" was the report given to patients if they requested their lab results. On 05/06/2022 at 12: 25 PM, Testing Personnel A confirmed the name and address of the laboratory, and normal values were not on the report.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual, and interview, the Laboratory Director failed to specify in writing, the responsibilities and duties (job descriptions) of the

	Technical Consultant, and Testing Personnel. Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 10/25/2021, showed there was no job descriptions for the Technical Consultant and Testing Personnel. According to the Laboratory Personnel Report, signed and dated by the Laboratory Director on 04/18/2022, there was 1 Technical Consultant and 2 Testing Personnel. On 05/06/2022 at 11:14 AM, Testing Personnel A stated there were no job descriptions in writing for the Technical Consultant and Testing Personnel.