Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2237074	02/05/2024
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	Recertification survey was conducted on February 1, 2024 to February 5, 2024. Spartan Medical Men's Health Clinic clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 review of proficiency testing (PT) records, and interview, the laboratory failed to verify accuracy of the Prostate-Specific Antigen (PSA) and Testosterone test at least twice annually for 2022 and 2023. Findings: Review of American Proficiency Institute (API) PT records showed the laboratory performed PT for the third event of 2023. No other API PT documentation of PT was available for review. On 02/01/2024 at 10:18 AM, Testing Personnel A stated they did not perform any PT in 2022 and they only performed PT once in 2023.
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 interview and review of quality control logs, patient logs, and the laboratory's Individualized Quality Control Plan (IQCP), the laboratory failed to follow their IQCP to run weekly (7 days) quality controls (QC) on the Qualigen FastPack IP System before reporting patient test results from 08/15/2021 to 11/30 /2023. This is a repeat deficiency from the initial survey performed 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 interview and review of quality control logs, patient logs, and the laboratory's Individualized Quality Control Plan (IQCP), the laboratory failed to follow their IQCP to run weekly (7 days) quality controls (QC) on the Qualigen FastPack IP System before reporting patient test results from 08/15/2021 to 11/30 /2023. This is a repeat deficiency from the initial survey performed 05/06/2022. Findings: Review of the laboratory's IQCP showed "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 QC logs for PSA showed controls were run on 08/26/2022 and not run again until 09/15/2022. Review of patient logs showed patients were tested on the following dates: 09/02/2022 - 5 patients 09/05/2022 - 1 patient 09/06/2022 - 2 patients 09/14 /2022 - 2 patients Review of QC logs for PSA showed controls were run on 09/21 /2022 and not run again until 10/03/2022. Review of patient logs showed patients were tested on the following dates: 09/30/2022 - 3 patients 10/01/2022 - 1 patient Review of QC logs for PSA showed controls were run on 10/03/2022 and not run again until 10/13/2022. Review of patient logs showed a patient was tested on the following date: 10/10/2022 - 1 patient Review of QC logs for PSA showed controls were run on 10/16/2022 and not run again until 10/30/2022. Review of patient logs showed patients were tested on the following dates: 10/24/2022 - 1 patient 10/27/2022 - 2 patients 10/28/2022 - 6 patients Review of QC logs for PSA showed controls were run on 10/30/2022 and not run again until 11/10/2022. Review of patient logs showed a patient was tested on the following date: 11/09/2022 - 1 patient Review of QC logs for PSA showed controls were run on 04/21/2023. The previous controls were run on 04/14/2023. One patient was tested on 04/21/2023 before both levels of controls (C1, C2) were run. Patient was tested at 9:15 AM C1 run at 7:55 AM C2 run at 9:21 AM Review of QC logs for PSA showed controls were run on 09/09/2023 and not run again until 09/20/2023. Review of patient logs showed a patient was tested on the following date: 09/16/2023 - 1 patient Review of QC logs for PSA showed controls were run on 10/05/2023 and not run again until 10/19/2023. Review of patient logs showed a patient was tested on the following date: 10/12/2023 - 1 patient Review of QC logs for Testosterone showed controls were run on 08/07/2022 and not again until 08/23/2022. Review of patient logs showed patients were tested on the following

	dates: 08/15/2022 - 1 patient 08/16/2022 - 3 patients Review of QC logs for Testosterone showed controls were run on 08/29/2022 and not run again until 09/11 /2022. Review of patient logs showed patients were tested on the following date: 09/05 /2022 - 3 patients Review of QC logs for Testosterone showed controls were run on 09 /11/2022 and not run again until 09/26/2022. Review of patient logs showed patients were tested on the following dates: 09/18/2022 - 1 patient 09/19/2022 - 1 patient 09/22 /2022 - 2 patients 09/23/2022 - 2 patients Review of QC logs for Testosterone showed controls were run on 10/03/2022 and not run again until 10/13/2022. Review of patient logs showed a patient was tested on the following date: 10/10/2022 - 1 patient Review of QC logs for Testosterone showed controls were run on 10/13/2022 and not run again until 10/27/2022. Review of patient logs showed patients were tested on the following dates: 10/20/2022 - 1 patient 10/21/2022 - 5 patients 10/24/2022 - 1 patient Review of QC logs for Testosterone showed controls were run on 10/30/2022 and not again until 11/10/2022. Review of patient logs showed a patient was tested on the following date: 11/07/2022 - 1 patient Review of QC logs for Testosterone showed controls were run on 12/15/2022 and not run again until 12/29/2022. Review of patient logs showed patients were tested on the following dates: 12/22/2022 - 3 patients 12/23/2022 - 4 patients Review of QC logs for Testosterone showed controls were run on 01/25/2023 and not run again until 02/04/2023. Review of patient logs showed patients were tested on the following dates: 02/01/2023 - 1 patient 02/02/2023 - 3 patients Review of QC logs for Testosterone showed controls were run on 06/01 /2023. The previous controls were run on 05/17/2023. One patient was tested on 06/01 /2023 before both levels of controls (C1, C2) were run. Patient was tested at 10:06 AM C1 run at 12:31 PM C2 run at 12:45 PM Review of QC logs for Testosterone showed controls were run on 06/15/2023. The previous controls were run on 06/08 /2023. One patient was tested on 06/15/2023 before both levels of controls (C1, C2) were run. Patient was tested at 10:32 AM C1 run at 10:08 AM C2 run at 10:46 AM Review of QC logs for Testosterone showed controls were run on 06/15/2023 and not run again until 06/29/2023. Review of patient logs showed patients were tested on the following dates: 06/22/2023 - 2 patients 06/23/2023 - 5 patients Review of QC logs for Testosterone showed controls were run on 06/15/2023 and not again until 06/29 /2023. Review of patient logs showed patients were tested on the following dates: 06 /22/2023 - 2 patients 06/23/2023 - 5 patients Review of QC logs for Testosterone showed controls were run on 07/13/2023 and not run again until 08/10/2023. Review of patient logs showed patients were tested on the following dates: 07/20/2023 - 3 patients 07/21/2023 - 3 patients 07/27/2023 - 3 patients 07/28/2023 - 3 patients 07/31 /2023 - 2 patients 08/03/2023 - 1 patient Review of QC logs for Testosterone showed controls were run on 10/05/2023 and not run again until 10/19/2023. Review of patient logs showed a patient was tested on the following date: 10/12/2022 - 1 patient Review of QC logs for Testosterone showed controls were run on 11/30/2023. The previous controls were run on 11/16/2023. Two patients were tested on 11/30/2023 before both levels of controls (C1, C2) were run. Patients were tested at 12:52 PM and 1:57 PM C1 run at 4:22 PM C2 run at 4:35 PM On 02/01/2024 at 11:30 AM, Testing Personnel A stated he thought controls were run but could not locate the missing documentation.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of Quality Assurance Assessment (QA) forms, and interview, the Laboratory Director failed to identify failures in the quality of laboratory services from 07/04/2022 to 01/012023. (See D6022)
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance Assessment (QA) forms, and interview, the Laboratory Director failed to identify failures in the quality of laboratory services from 07/04/2022 to 01/01/2023. Review of the Quality Assurance Assessment forms showed the forms were signed by the Laboratory Director on 07/04/2022, 08/01/2022, 09/05/2022, 10/03/2022, 11/07/2022, 01/02/2023, 02/06/2023, 03/06/2023, 04/03 /2023, 05/01/2023, 06/05/2023, 07/03/2023, 08/07/2023, 09/04/2023, 10/02/2023, 11 /06/2023, and 01/01/2024. Review of the laboratory's procedure titled Quality Assurance Assessment Program noted, "The laboratory director oversees the implementation of this QA Assessment plan and helps identify and correct problems as they occur." The laboratory's QA plan failed to identify the laboratory was not performing proficiency testing (See D5217), and failed to identify the laboratory failed to follow their Individual Quality Control Plan (IQCP) by not performing quality controls on Prostate-Specific Antigen (PSA) and Testosterone weekly (See D5445) On 02/01/2024 at 10:18 AM, Testing Personnel A stated they did not perform any PT in 2022 and they only performed PT once in 2023. On 02/01/2024 at 11:30 AM, Testing Personnel A stated he thought controls were run but could not locate the missing documentation.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on interview, review of job descriptions, review of the laboratory's Allegation of Compliance from the initial survey on 05/06/2022, review of quality control logs, patient logs, and the Daily Environment and Quality Control Log, the Technical Consultant failed to ensure acceptable levels of analytic performance were maintained from June 2022 to January 2024. (See D6042)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on interview, review of job descriptions, review of the laboratory's Allegation of Compliance from the initial survey on 05/06/2022, review of Quality Control (QC) logs, patient logs, and the Daily Environment and Quality Control Log, the Technical Consultant failed to ensure acceptable levels of analytic performance were maintained from June 2022 to January 2024. Findings: Review of the Technical Consultant Responsibilities and Job Description noted the Technical Consultant was responsible to "Establish a quality control program appropriate for the testing performed, establish the acceptable levels of analytical performance, and ensure these levels were maintained throughout the testing process. Review of the Allegation of Compliance, signed by the Laboratory Director on 06/16/2022, from the initial survey on 05/06 /2022 noted "All controls will be performed, at the latest, seven days apart. If this does not occur, for supply reasons, no patient testing will be performed, until recalibration and two controls have first been performed. Control performance dates will be documented on current Lab Environmental Log Sheet allowing for all staff to document this information, to see if/when it is time to perform controls." The Allegation of Compliance also noted the "Technical consultant will review each week, to confirm compliance." Review of the quality control logs and patient logs revealed the quality control for Prostate-Specific Antigen (PSA) and Testosterone were not performed weekly as indicated in the laboratory's Individual Quality Control Plan. (See D5445) Review of the laboratory's quality control logs and the Daily Environmental and QC Log revealed the quality controls for PSA and Testosterone were not documented each time the controls were run. Review of the Daily Environmental and QC Logs showed there was no documentation to indicate the Technical Consultant reviewed the logs. On 02/01/2024 at 11:30 AM, Testing Personnel A stated he thought controls were run but could not locate missing documentation. On 02/01/2024 at 12:00 PM, Testing Personnel A stated he did not record every time controls were run on the Daily Environmental and QC Log.