Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2250361	05/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Montgomery Mens Health, Llc	4780 Woodmere Blvd, Montgomery, AL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Director of Compliance (DoC), the laboratory failed to ensure the Laboratory Director (or designee) and the analyst signed the PT attestation statements. This was noted for one of the six events reviewed from 2023-2025. The findings include: 1. A review of the 2023-2025 API PT records revealed the Laboratory Director (or designee) and the analyst did not sign the attestation statement for the 2024 Chemistry Core 3rd Event. 2. The DoC confirmed the above findings during the exit conference on 05-08-2025 at 1:30 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on a review of the 2023-2025 Daily Environmental and Quality Control (DEQC) logs, and an interview with the Director of Compliance (DoC), the laboratory failed to ensure room temperature, refrigerator temperature and humidity were recorded each day of patient testing. The surveyor noted the room temperature, refrigerator temperature and humidity were not recorded for two of the 31 days in January 2024. The findings include: 1) A review of the January 2024 DEQC log revealed the laboratory failed to monitor and record the temperature, refrigerator temperature and humidity of the laboratory on 01-17-2024 and 01-18-2024 when nine patients tests were performed. 2. A further review of the January 2024 DEQC log revealed the laboratory's specified acceptable ranges, as follows: A) RT (15-32 degrees Celsius) B) Humidity (10-80 Percent) C) Refrigerator (2-8 degrees Celsius) 3) The DoC confirmed the above findings during the exit conference on 05-08-2025 at 1: 30 PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Qualigen Fast Pack System (QFPS) Testosterone calibration procedure, the Calibration-Verification (C-V) records, and an interview with the Director of Compliance (DoC), the laboratory failed to perform and document C-V procedures at least once every six months as required by CLIA regulations. The surveyor noted no documentation for three of the five C-Vs due from 2023-2025. The findings include: 1. A review of the QFPS calibration procedure revealed Testosterone was calibrated with one calibrator. All analytes calibrated with less than three calibrators must have a semi-annual C-V, as per CLIA regulatory requirements. 2. A review of the Testosterone records revealed documentation of C-V's performed on 03-31-2023 and 02-29-2025 only. There was no documentation of Testosterone C-V due during the following periods: A) September 2023 B) March 2024 C) September 2024 3. During an interview on 05-08-2025 at approximately 11:34 AM, the DoC stated the previous laboratory management failed to ensure C-Vs were performed every six months, as per CLIA requirements.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on reviews of the Qualigen Fast Pack System Quality Control (QC) logs, the laboratory's Individual Quality Control Plan (IQCP) and an interview with the Director of Compliance (DoC), the laboratory failed to ensure two levels of QC were performed and documented each week of patient testing as per the Quality Control Plan in the IQCP. The surveyor noted there was no documentation of QC the week of March 10-14, 2025, one out of full four weeks in March 2025. The findings include: 1. A review of the Qualigen Fast Pack System QC logs revealed the laboratory failed to perform the required QC prior to patient testing from March 10-14, 2025. There were 14 patient tests performed during this period. 2. A review of the IQCP revealed a requirement to perform two levels of QC once per week or whenever calibration was performed. 3. The DoC confirmed the above findings during the exit conference on 05-08-2025 at 1:30 PM.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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 a review of Personnel records and an interview the Director of Compliance (DoC), the Technical Consultant (TC) failed to assess competency at least semi-annually during the first year of patient testing. This was noted for one of three Testing Personnel (TP) listed on the CMS 209 (Laboratory Personnel Report) performing moderate complexity testing from 2023-2025. The findings include: 1. A review of Personnel records revealed TP3 had no evidence of semi-annual competency assessment completed by the TC for 2023-2025. 2. The DoC confirmed the above findings during the exit conference on 05-08-2025 at 1:30 PM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview the Director of Compliance

	(DoC), the Technical Consultant (TC) failed to assess competency of Testing Personnel (TP) at least annually. This was noted for one of the three TP listed on the CMS 209 (Laboratory Personnel Report) performing moderate complexity testing from 2023-2025. The findings include: 1. A review of Personnel records revealed TP3 had no evidence of annual competency assessment completed by the TC for 2023-2025. 2. The DoC confirmed the above findings during the exit conference on 05-08-2025 at 1:30 PM.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) (b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on reviews of personnel records, American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Director of Compliance (DoC), the laboratory failed to ensure required initial training documentation was completed for one of the three Testing Personnel (TP) listed on the CMS 209 (Laboratory Personnel Report) prior to performing moderate complexity patient testing. The findings include: 1. A review of the 2023-2025 personnel records revealed TP3 had no documentation of initial training appropriate for the moderate complexity testing performed in the laboratory. 2. A review of the API PT records revealed TP3 performed the 2024 API First Event as indicated on the attestation form. 2. During the exit conference on 05-08-2025 at 1:30 PM, the DoC confirmed the above findings.