Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 43D2196944	**(X3) Date Survey Completed** 09/19/2024
Name of Provider or Supplier Limitless Male Medical Clinic	**Street Address, City, State** 5919 South Remington Place # 200, Sioux Falls, SD	
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	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 9/19/24. Limitless Male Medical Clinic laboratory was found not in compliance with the following requirements: D2015, D6046
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of the required documentation related to the processing of three of three proficiency testing (PT) events reviewed (2023 Chemistry Core 3rd event; 2024 Chemistry Core 1st event; 2024 Chemistry Core 2nd event). That documentation would ensure the results submitted for evaluation had been the results obtained by the laboratory processing the PT samples. Findings include: 1. Review on 9/19/24 of the laboratory's 2023 and 2024 American Proficiency Institute (API) PT event records revealed: *The laboratory had subscribed to PT events through API. *PT specimens were processed, and the results submitted electronically via the company's website upon completion of testing. *The laboratory had the ability to print a copy of the final PT results that were submitted for evaluation. *The laboratory had not retained copies of the final

	electronically submitted results for evaluation for the following events: -2023 API Chemistry Core 3rd event -2024 API Chemistry Core 1st event -2024 API Chemistry Core 2nd event Review of the laboratory's PT policy, last reviewed on 11/4/23 revealed, "Copies of the final report form will be retained as documentation that the final PT specimen was treated as a patient specimen and to document transcription errors, if any." Interview on 9/19/24 at 10:30 a.m. with the training and development manager E revealed: *PT results were electronically reported after PT samples had been processed. *The laboratory could print a copy of all final PT results submitted for evaluation. *The laboratory had not printed copies of the final submitted PT results.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, technical consultant A failed to assess the competency of two of two testing personnel (B and C) for the test methods they had been performing under the laboratories certificate. Competency assessments helps to ensure the laboratory staff have the knowledge and skills to complete assigned duties correctly. Findings include: 1. Review on 9/19/24 of the laboratory's Centers for Medicare and Medicaid Services form 209 Laboratory Personnel, signed by laboratory director D on 9/18/24, revealed: *Laboratory staff A had been listed as technical consultant. *Laboratory staff B and C had been listed as testing personnel. *Training and development manager E was not listed as a technical consultant. 2. Review of the laboratory's employee files for laboratory staff revealed: *Testing Personnel B had competency evaluations performed on 12/23 and 5/24. *Testing Personnel C had a competency evaluation performed on 5/24. *Competency evaluations for testing personnel B and C had been completed by laboratory training and development manager E. *Technical consultant A had not completed the competency evaluations for testing personnel B and C. Review on 9/19/24 of technical consultant A's delegated duties revealed, "Technical consultant is responsible for assessment and maintenance of competency of all individuals who conduct pre-analytical, analytical and post analytical phases of testing and identify necessity for remedial training or continuing education to improve or enhance skills." Review on 9/19/24 of the laboratory's competency assessment policy, last revised on 11/4/23, revealed that competency assessments were to be performed on testing personnel yearly, but it had not stated who had been responsible for completing them. Interview on 9/19/24 at 10:45 a.m. with training and development manager E revealed: *He confirmed he had performed the competency assessments. *He confirmed he had been trained as a medical aid. *He confirmed he did not qualify as a technical consultant. *He confirmed technical consultant A had not been involved in the competency assessment process. *He had been unaware that technical consultant A had been responsible for completing competencies. Technical Consultant A and laboratory director D had been unavailable for interview at the time of the survey.