Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2092042	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
American Wellness & Rehab Clinic Llc	677 West 5300 South, Murray, UT	

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**
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual and an interview with testing personnel 1 (TP1), the laboratory failed to include criteria for specimen acceptability and rejection, limitations in the test methodology, reference intervals, and a description of the course of action to take if a test system becomes inoperable in their procedure manual. The laboratory performs approximately 4000 endocrinology tests a year. Findings include: 1. Review of the policy and procedure manual revealed a lack of criteria for specimen acceptability and rejection. 2. Review of the policy and procedure manual revealed a lack of reference limitations in the test methodology,

	including interfering substances. 3. Review of the policy and procedure manual revealed a lack of reference intervals. 4. Review of the policy and procedure manual revealed a lack of and a description of the course of action to take if a test system becomes inoperable. 5. Interview with the TP1 on 12/04/2024 at 3:22 PM confirmed the laboratory failed to include criteria for specimen acceptability and rejection, limitations in the test methodology, reference intervals, and a description of the course of action to take if a test system becomes inoperable in their policy and procedure manual. _
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 document review, direct observation, and interview with the testing personnel 1 (TP1), room temperature and humidity of the laboratory was not monitored and documented since the laboratory began patient testing on 11/20/2023. The laboratory performs approximately 4000 endocrinology tests a year. Findings include: 1. Document review of the Tosoh Bioscience AIA-360 instrument specifications revealed the analyzer required an operating environment between 15C to 30C and relative humidity between 40% and 80%. 2. Direct observation of the laboratory on 12/04/2024 at 13:45 PM failed to locate a thermometer, hygrometer, and a laboratory conditions log. 3. In an interview on 05/23/2024 at 12:45 PM, TP1 confirmed room temperature and humidity were not monitored and documented for the Tosoh Bioscience AIA-360. _
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation of the laboratory and interview with the testing personnel 1 (TP1), the laboratory failed to properly label two of two open bottles of Liquichek Immunoassay Premium Controls, levels 1 and 3, with open dates and expiration dates. The laboratory performs approximately 4000 endocrinology tests a year. Findings include: 1. Direct observation of the laboratory on 12/04/2024 at approximately 2:45 PM revealed two of two open bottles of Liquichek Immunoassay Premium Controls, levels 1 and 3, used in the analysis of -human chorionic gonadotropin and progesterone testing with the Tosoh Bioscience AIA-360 instrument were not labeled

	with opened dates and expiration dates. 2. Interview with the TP1 on 12/04/2024 at approximately 2:45 PM confirmed the open bottles of controls were not labeled with opened dates and expiration dates. _
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on document review and interview with the testing personnel 1 (TP1), the laboratory failed to test two different concentrations of control materials each day patient specimens are tested since the laboratory began patient testing on 11/20/2023. The laboratory performs approximately 4000 endocrinology tests a year. Findings include: 1. Document review of laboratory control logs revealed only one control level of Liquichek Immunoassay Premium Controls were analyzed each day patient testing occurred for the analysis of -human chorionic gonadotropin and progesterone testing with the Tosoh Bioscience AIA-360 instrument. 2. Interview with the TP1 on 12/04/2024 at approximately 2:40 PM confirmed only one level of Liquichek Immunoassay Premium Controls were analyzed each day patient testing occurred. _
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records review and interview with testing personnel 1 (TP1), the laboratory failed to verify the stated values of quality control materials for new lot numbers of Liquichek Immunoassay Premium Controls levels 1, 2, and 3 since the laboratory began patient testing on 11/20/2023. The laboratory performs approximately 4000 endocrinology tests a year. Findings include: 1. The laboratory quality control records failed to document the laboratory verified new quality control lot numbers of Liquichek Immunoassay Premium Controls levels 1, 2, and 3 against the previous lot number values and compared to the manufacturer's stated results of controls to confirm the new lot number mean and ranges were acceptable prior to use.

	2. Interview with the TP1 on 12/04/2024 at approximately 2:55 PM confirmed new lots of controls ranges were not verified by the laboratory prior to use. _
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 with testing personnel 1 (TP1) the laboratory failed to state the units of measurement for -human chorionic gonadotropin and progesterone test results on test reports. The laboratory performs approximately 4000 endocrinology tests annually. Findings include: 1. Record review of the test reports found no units of measurement listed on patient test reports for -human chorionic gonadotropin and progesterone tests performed by the laboratory. 2. Interview with TP1 on 10/04/2024 at approximately 4:05 PM, confirmed the test reports for -human chorionic gonadotropin and progesterone failed to list the units of measurement. _
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel 1 (TP1) the laboratory failed to include reference intervals for -human chorionic gonadotropin and progesterone test results on test reports. The laboratory performs approximately 4000 endocrinology tests annually. Findings include: 1. Review of test reports for -human chorionic gonadotropin and progesterone tests revealed that no reference intervals were available on the final test reports. 2. Interview with the TP1 on 12/04/2024 at approximately 4:00 PM confirmed that test reports do not include reference intervals.