Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2092555	12/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Restoration Medical Clinic, Pc	1050 Revolution Mill Drive, Studio 7a, Greensboro, NC	

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 review of laboratory procedures and interview with general supervisor (GS) 12/14/21, the laboratory procedure for Buprenorphine (BUP) failed to specify the cut-off value used by the laboratory and failed to include the levels and values of QC material used. Findings: 1. Review of laboratory procedure "IR500 Buprenorphine Enzyme Immunoassay" revealed "Intended Use: The Lin-Zhi International (LZI) Buprenorphine Enzyme Immunoassay is intended for the qualitative and semi-qualitative determination of norbuprenorphine (buprenorphine metabolite) in human

	urine at a cutoff value of 5 and 10 ng/mL...". The procedure failed to specify the cut-off value used by the laboratory. 2. Review of laboratory procedure "IR500 Buprenorphine Enzyme Immunoassay" revealed "Material Required: Reagent, Controls, Calibrators...LZI Single QC Material, Buprenorphine LZ0272, LZ0274...". The procedure included the part numbers of the QC material and failed to include the levels and values of QC material used. Interview with GS at approximately 3:00 p.m. confirmed the BUP procedure was not complete and current.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with GS 12/14/21, the laboratory failed to validate the performance specifications for the testing performed on the IR-500 analyzer since patient testing began in September of 2020. Findings: Review of laboratory record "MEMO TO FILE" revealed "On September 1, 2020, (current laboratory name) laboratory moved location to a larger room next door...Screening testing was switched to IR-500 #130210. This instrument was validated on May 2016 under the laboratory (previous laboratory name). This validation has been reviewed and approved by the (current laboratory name) Laboratory Director.". The validation of performance specifications performed by a previous laboratory failed to meet the validation of performance specifications for the testing performed on the IR-500 analyzer. Interview with GS at approximately 11:00 a.m. confirmed the current laboratory failed to validate the performance specifications for the testing performed on the IR-500. She stated they were told that they could use the data obtained from the previous laboratory's validation.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with GS 12/14/21, the laboratory

	failed to validate the performance specifications for the Ethyl Alcohol testing performed on the IR-500 analyzer and all toxicology testing performed on the LCMS analyzer before patient testing began in September of 2020. Findings: 1. The laboratory failed to validate the performance specifications for the Ethyl Alcohol testing performed on the IR-500 analyzer. Review of laboratory record "MEMO TO FILE" revealed "On September 1, 2020, (current laboratory name) laboratory moved location to a larger room next door...Screening testing was switched to IR-500 #130210. This instrument was validated on May 2016 under the laboratory (previous laboratory name). This validation has been reviewed and approved by the (current laboratory name) Laboratory Director.". The validation of performance specifications performed by a previous laboratory failed to meet the validation of performance specifications for the testing performed on the IR-500 analyzer. Interview with GS at approximately 11:00 a..m. confirmed the laboratory failed to validate the performance specifications for the Ethyl Alcohol testing performed on the IR-500. She stated they were told that they could just use the data obtained from the previous laboratory's validation. 2. The laboratory failed to validate the performance specifications for all toxicology testing performed on the LCMS analyzer. Review of laboratory record "MEMO TO FILE" revealed "On September 1, 2020, (current laboratory name) laboratory moved location to a larger room next door...Confirmation testing was switched to LCMS serial #L20875350055. This instrument was validated on September 2018 under the laboratory (previous laboratory name). This validation has been reviewed and approved by the (current laboratory name) Laboratory Director.". The validation of performance specifications performed by a previous laboratory failed to meet the validation of performance specifications for the testing performed on the LCMS analyzer. Interview with GS at approximately 11:00 a..m. confirmed the laboratory failed to validate the performance specifications for all toxicology testing performed on the LCMS analyzer. She stated they were told that they could just use the data obtained from the previous laboratory's validation.