Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2020241	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Regional Orthopaedics	110 Patrick Court, Rocky Mount, 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 procedure manual and interview with testing personal (TP) #1 3/26/21, the laboratory failed to have a procedure for entering patient test results in the patient medical record. Findings: Review of laboratory procedure manual revealed no procedure for the laboratory's system of entering patient test results into the patient medical record. Interview with TP#1 at approximately 12:00 p. m. confirmed the laboratory did not have a procedure for entering test results into the

	patient medical record. She stated that reports are printed from the analyzer, a barcode is put on the report, and the report is then scanned into Athena which attaches it to the patient's medical record, but they did not have a procedure for this process.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 laboratory calibration records and interview with technical consultant (TC) 3/26/21, the laboratory failed to perform 6 month calibration verifications on 4 of 9 analytes tested on the Easy RA analyzer since August of 2018, approximately 32 months since patient testing began. Findings: The laboratory performs qualitative urine drug screens for Amphetamine (AMP), Barbiturate (BARB), Benzodiazepine (BENZ), Cocaine (COC), Methadone (MTD), Opiate (OPI), Oxycodone (OXY), and Cannabinoid (THC). Review of 2018, 2019, 2020, and 2021 laboratory calibration records revealed the laboratory performs a one-point calibration for the qualitative analytes, AMP, BARB, COC and OPI. The calibration records failed to document a calibration verification using a two-point calibration method every 6 months as required. Interview with TC at approximately 11:00 a.m. confirmed the laboratory did not perform calibration verifications for the 4 analytes as required.