Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2164764	08/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Msrc, Llc	102 Patrick St Plaza, Charleston, WV	

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	An announced, on site, routine recertification survey was conducted at MSRC, LLC on August 18, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are as follows:
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 record review, lack of documentation, and interview the laboratory failed to perform and document calibration verification every 6 months for 10 of 10 analytes on the Biolis 24i analyzer for 2020 and 2021. Findings: 1. Review of 2020 and 2021 calibration records revealed all 10 analytes are calibrated with 2 levels of calibrator material at least weekly. 2. No documentation was found that calibration verification was performed on the 10 Biolis 24i analytes from February 2020 thru the date of the survey. 3. The laboratory director and the technical consultant confirmed during the exit interview on 8/18/21 at 12:00 PM that the calibration verification procedures had not been performed or documented.
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 review of policies and procedures (P&P), lack of documentation, record review, and interview the laboratory failed to establish the criteria for the acceptance of quality control values for 10 of 10 analytes tested on the Biolis 24i analyzer. Findings: 1. Review of P&P revealed a lack of specified acceptable ranges for quality control (QC) materials for amphetamines, methamphetamine, cocaine, benzodiazepine, buprenorphine, opiates, oxycodone, methadone, creatinine, and PH testing on the Biolis 24i analyzer. 2. Review of quality control records (April 2021 thru July 2021) identified: runs of 2 levels of QC for amphetamines, methamphetamine, cocaine, benzodiazepine, buprenorphine, opiates, oxycodone, and methadone and runs of 3 levels of QC for creatinine and PH on days of patient testing. 3. The laboratory director and technical supervisor confirmed during the exit interview, on 8/18/21 at 12:00 PM, that there was no documented acceptable ranges for the acceptance of QC on the Biolis 24i analyzer.