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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 51D2164764 | (X3) Date Survey Completed 08/20/2025 |
| Name of Provider or Supplier Msrc, Llc | Street Address, City, State 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 |
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| D0000 | A routine recertification survey was completed at MSRC, LLC. on August 20, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below. |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing (PT) evaluation reports, laboratory PT records, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to evaluate unacceptable scores for toxicology analytes in one of two UDS screening testing events and one of two DMPM confirmation testing events in 2024. Findings: 1. Review of four 2024 CAP PT evaluation reports (UDS-B, -C and DMPM-A,-B) revealed the following unacceptable scores: For UDS-C 2024 specimen UDS-11, laboratory reported a positive methamphetamine screening result that CAP graded as unacceptable. For DMPM-B 2024 specimen 06, laboratory reported a quantitative result for pregabalin that CAP graded as unacceptable. 2. Review of the laboratory PT records for 2024 revealed no documented evaluation of the two unacceptable analyte scores. 3. During an interview, 8/20/25 at 9:00 AM, the TS stated that no documented evaluation for the two unacceptable results could be located.</p> |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p> |

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the current laboratory test menu, College of American Pathologists (CAP) proficiency testing (PT) records, laboratory quality assessment (QA) documents, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to verify the accuracy for 8 of 8 toxicology analytes tested on the Biolis 24i screening panel from January 2025 thru date of survey. Findings: 1. Review of the current test menu on the Biolis 24i toxicology analyzer identified an 8 analyte screening panel (buprenorphine, amphetamine, methamphetamine, benzodiazepine, cocaine metabolite, methadone, opiate, and oxycodone). 2. Review of CAP PT records for 2025 revealed the 8 analytes on the Biolis 24i screening panel were not enrolled in commercial PT. All 8 are unregulated analytes and not included in Subpart I. 3. Review of laboratory QA documents revealed no documentation that the laboratory performed an alternate accuracy verification from January 2025 thru date of survey for the 8 analytes. 4. During an interview, 8/20/25 at 10:00 AM, the TS stated no commercial PT or alternative verification for the 8 Biolis 24i analytes had taken place yet in 2025.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of toxicology policies and procedures, quality assessment (QA) documents, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to follow established policies for monitoring and correcting problems in the general laboratory systems from October 2024 thru date of survey. Findings: 1. Review of laboratory QA policies identified the following elements of the general laboratory systems to be monitored on a monthly basis and findings documented on the "MSRC Monthly Quality Assurance Monitor": investigation of unacceptable proficiency testing (PT) results and documentation alternative PT assessment was completed as needed. 2. Review of MSRC Monthly Quality Assurance Monitor (October 2024 thru date of survey) revealed no documentation that the performance of the general laboratory systems QA involving the investigation of unacceptable PT scores and the alternative PT assessment occurred. Refer to D5211 and D5217. 3. During an interview, 8/20/25 at 12:00 PM, the TS stated the general laboratory systems QA had not been performed since October 2024.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

This STANDARD is not met as evidenced by:

Based on review of toxicology policies and procedures, quality control (QC) records for the Sciex LCMS analyzer, Main Panel Batch Run Forms, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to (d)(10)(ii) document the evaluation and verification of acceptability for two of two new lots of commercially assayed QC in 2025. Findings: 1. Review of "Analytic Procedure V 2.0" for LCMS testing identified the process for preparation, evaluation, and verification of acceptability for new lots of QC materials (QC Working Stock) from commercially prepared analytical reference standards (Cerilliant). 2. Review of QC records and Main Panel Batch Run Forms (January 2025 thru date of survey) revealed the following new lots of QC Working Stock and the date put into use: lot 29 June 25 put into use 3/3/2025 lot 01 Nov 25 put into use 6/2/2025 3. No documentation of the evaluation and verification of acceptability for the two new lots of QC material could be located. 4. During an interview, 8/20/2025 at 11:00 AM, the TS stated that no evaluation and verification of acceptability for the two new lots of QC materials could be located.