| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 51D2164764 | 01/22/2020 |
| **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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of written laboratory policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to establish written policies and procedures to assess employee competency and initial training of testing personnel. Findings: 1. A review of written laboratory policies and procedures could not locate a written policy or procedure for assessing employee competency or initial training of testing personnel. 2. A review of written policies and procedures identified an employee assessment form for initial training and employee competency that contains all six of the required elements. 3. An interview with TS, on 1/22/2020 at approximately 9:40 AM, confirmed the findings. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory written policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to establish a written policy |

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| | and procedure for monitoring, assessing, and correcting problems of the general laboratory systems. Findings: 1. No written policy or procedure for the Quality Assessment (QA) of the general laboratory systems could be located. This includes the monitoring and assessment of confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing evaluation. 2. An interview with TS1, on 01/22/2020 at approximately 10:30 AM, confirmed that no written policy or procedure for the QA of the general laboratory systems could be located. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of written laboratory policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to establish a written policy or procedure for (8) specimen referral. Findings: 1. A review of written laboratory policies and procedures identified that no written policy or procedure for specimen referral could be located. 2. An interview with TS1, on 01/22/2020 at approximately 10:00 AM, confirmed that no written policy or procedure for specimen referral to QLabs for confirmation testing could be located. |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(a)<br><br>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 preanalytic systems specified at 493.1241 through 493.1242.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory written policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to establish a written policy or procedure for monitoring, assessing, and correcting problems identified in the preanalytic systems. Findings: 1. No written policy or procedure for the Quality Assessment (QA) of preanalytic systems could be located. QA of preanalytic systems includes test requests and specimen submission, specimen handling, and specimen referral. 2. An interview with TS1, on 01/22/2020 at approximately 10:30 AM, confirmed that no written policy or procedure for the QA of preanalytic systems could be located. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of written policies and procedures and an interview with the technical supervisor (TS1) , the laboratory failed to establish a written policy or procedure for (14) the course of action to take if a test system becomes inoperable. Findings: 1. A review of laboratory written policies and procedures identified that a written policy or procedure for the course of action to take if a test system becomes inoperable could not be located. 2. An interview with TS1, on 01/22/2020 at approximately 10:00 Am, confirmed that no policy or procedure for inoperable test systems could be located. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based upon a review of written laboratory policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to have the current laboratory policies and procedures signed and dated by the current laboratory director before use. Findings: 1. A review of the current laboratory policies and procedures identified that these policies and procedures had not been signed and dated by the current laboratory director. 2. An interview with TS1, on 01/22/2020 at approximately 10:30 AM, confirmed that the current laboratory policies and procedures had not been signed and dated by the laboratory director before use. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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 |

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| | electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory temperature and humidity logs, a tour of the laboratory, and an interview with the technical supervisor (TS1), the laboratory failed to monitor and document the (2) temperature and (3) humidity for reliable test system operation and reagent storage with an NIST certified calibrated thermometer. Findings: 1. A review of the laboratory temperature and humidity logs identifies acceptable temperature and humidity ranges for the laboratory and provides a form for the documentation of the daily temperatures and humidity. a. Room Temperature 15 to 30 degrees Celsius b. Humidity 30 to 80 percent c. Refrigerator Temperature 2 to 8 degrees Celsius 2. A review of the laboratory temperature and humidity logs showed the documentation of temperature and humidity conditions on days of testing in the laboratory. Temperature and humidity logs reviewed were from November 2019, December 2019, and January 2020. 3. No documentation of the thermometers and hydrometer NIST certified calibration or traceability could be located. a. A Taylor thermometer model 3507T was in use for refrigerator temperature monitoring. b. A Therm Pro TP50 thermometer/hydrometer was in use for room temperature and humidity monitoring. 4. An interview with TS1, on 01/22/2020 at approximately 10: 40 AM, confirmed that no NIST certified calibration or traceability documentation could be located. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory written policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to establish a written policy or procedure for the Quality Assessment (QA) of analytic systems. Findings: 1. No written policy or procedure for the QA of analytic systems could be located. This includes the following: test procedures and procedure manuals, test systems/equipment /supplies, establishment and verification of performance specifications, maintenance and function checks, calibration and calibration verification procedures, control procedures, comparison of test results, corrective action, and test records. 2. An interview with TS1, on 01/22/2020 at approximately 10:30 AM, confirmed no written policy or procedure could be located. |
| **D5821** | TEST REPORT<br>CFR(s): 493.1291(k)<br><br>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of written laboratory policies and procedures, the laboratory failed to establish a system to identify and maintain corrected patient reports. Findings: 1. No written policy or procedure regarding corrected patient reports could be located. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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 postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of written laboratory policies and procedures and an interview with the technical supervisor (TS1), the laboratory failed to establish a written policy or procedure for the Quality Assessment (QA) of postanalytic systems. Findings: 1. No written policy or procedure for the QA of postanalytic systems could be located. This includes test reports. 2. An interview with TS1, on 10/22/2020 at approximately 10:30 AM, confirmed that no written policy or procedure for the QA of postanalytic systems could be located. |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the written laboratory policies and procedures, the laboratory director (LD) failed to ensure the laboratory had established all the required structures and processes necessary to provide accurate and reliable test results. Findings: 1. A review of the laboratory written policies and procedures revealed that the current policies and procedures had not been signed and dated by the LD before use in the laboratory daily operations. Refer to D5407. 2. A review of the laboratory written policies and procedures identified the lack of an established system to identify and maintain corrected patient reports. Refer to D5821. 3. A review of the laboratory written policies and procedures identified that no description of the course of action to take if a test system becomes inoperable could be located. Refer to D5403. 4. A review of written laboratory policies and procedures established that no written policy or procedure for the Quality Assessment (QA) of the general laboratory systems, preanalytic system, analytic system, and postanalytic system could be located. Refer |

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| | to D5291, D5391, D5791, and D5891. 5. A review of written laboratory policies and procedures identified that no written policy or procedure for the assessment of testing personnel competency and initial training could be located. Refer to D5209. 6. A review of written laboratory policies and procedures identified that no written policy or procedure for specimen referral to QLabs for confirmation testing could be located. Refer to D5311. |