| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 25D2099996 | 02/01/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Medplus Urgent Clinic, Llc | 874 Barnes Crossing Road, Tupelo, MS | |

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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| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory proficiency testing event records from 2019, 2020 and 2021 and confirmation with Technical Consultant/Lab Director (TC/LD) and testing personnel (TP) #1 at 5:30 p.m. on the day of survey, the laboratory failed to retain all proficiency records to include but not limited to results, attestation statements, submitted results and analyzer printouts. Findings include: 1. Review of records 3rd event of 2019, 1st, 2nd and 3rd events for 2020 and 2021 proficiency testing records revealed the laboratory did not retain the following: a. Report sheet /submitted result sheets for 3rd event of 2019, 2nd and 3rd events of 2020 and 2nd and 3rd events of 2021 for COVID SARS 2 proficiency testing. b. Attestation statement for 3rd event of 2019; 1st, 2nd, 3rd events of 2020; and 2nd, 3rd events of 2021 for COVID SARS 2 proficiency testing. c. Analyzer printouts for 1st, 2nd and 3rd events of 2020 and 2nd and 3rd events of 2021 2. Interview with TP #1 and the laboratory TC at 5:30 p.m. on 2/1/22 confirmed that the listed proficiency records were not retained after completion of each proficiency event. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory proficiency records from 2019, 2020 and 2021 and |

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| | interview with the technical consultant/laboratory director (TC/LD) and testing personnel (TP) #1 at 5:30 p.m., on the day of survey (2/1/22), the laboratory failed to verify the accuracy of the complete respiratory panel testing at least twice annually for year 2021. Findings Include: 1. Review of the proficiency records from 2019, 2020 and 2021 revealed the QIAstat -DX Respiratory Panel had not been verified as accurate for the year 2021. The QIAstat-DX Respiratory Panel includes the following elements: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus A+B, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4. Respiratory Syncytial Virus A+B, Rhinovirus /Enterovirus, SARS-CoV-2, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae 2. During an interview with the TC/LD and TP #1 at 5:30 p.m. on 2/1/22, confirmed the accuracy had not been verified on the complete Respiratory Panel performed on the QIAGEN QIAstat-DX analyzer. Only the SARS-CoV-2 had been verified for accuracy by participating in proficiency testing twice in 2021. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of records for the Biosite Triage Meter analyzer, lack of documentation of verification of performance specifications, and interview with testing personnel (TP) #1 and the technical consultant/ laboratory director(TC/LD) at 6:00 p.m. on 2/1/22, the laboratory failed to ensure that performance specifications including comparison studies were performed prior to testing patients. The Biosite Triage Meter was put back into use on 4/10/21 after being out of operation for several years. Findings: 1. Review of the Triage Meter records for the analyzer put into use on 4/10/21 revealed no documentation of a method comparison study performed. According to surveyor notes the Triage Meter, which the laboratory uses to tests troponin, myoglobin, CKMB and D-dimer had not been used since before the last survey on 8/22/19. 2. Interview with TP #1 and the TC/LD at 6:00 p.m. on 2/1/22 revealed no method comparison had been performed for the troponin, myoglobin, CKMB and D-dimer tested on the Biosite Triage Meter before testing patients on 4/10/21. . |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Biosite Triage Meter chemistry laboratory records, lack of documentation and interviews with testing personnel (TP) #1 and the technical consultant/laboratory director (TC/LD) at 6:30 p.m. on 2/1/22, the laboratory failed to perform initial calibration verification during the installation of the Biosite Triage Meter put in use on 4/10/21 and every 6 months for D-dimer, troponin, myoglobin and CKMB as required by the manufacturer. Findings include: 1. Review of the Biosite Triage records revealed the meter was put back into use on 4/10/21. 2. According to surveyor records the instrument had not been used since before 8/22/19. 3. There were no records of calibration verification performed for D dimer, troponin, myoglobin or CKMB. a. There was no documentation of initial calibration verification performed on the Biosite Triage meter during installation on 4/10/21. b. There was no documentation of any 6 month calibration verifications. 4. Calibration verification is required by the manufacturer initially and every 6 months on the Biosite Triage Meter for all tests performed. 5. TP #1 and the TC/LD confirmed in interview at 6:30 p.m. on 2/1/22 that there were no calibration verifications documented for D-dimer, myoglobin, troponin and CKMB. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory testing personnel (TP) records available on 2/1/22, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with the technical consultant/laboratory director (TC/LD) and testing personnel (TP) #1, the laboratory director had not ensured that all testing personnel as listed on the CMS 209 personnel form had received the appropriate documented training prior to performing |

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| | moderate complexity testing on the QIAGEN QIAstat-DX Analyzer which is used to test respiratory panels (including SARS-CoV-2) that was installed on 2/6/21 in the laboratory. Findings Include: 1. Based on lack of training documentation available the day of survey, testing personnel had not been trained on the new QIAstat-DX analyzer prior to performing testing on patients beginning on 2/6/21. 2. An interview with the TC/LD and TP #1 at 5:30 p.m. on 2/1/22 confirmed that no initial training had been documented for all testing personnel who perform testing on the QIAGEN QIAstat-DX Respiratory analyzer prior to testing patients on 2/6/21. |