

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2099996	<b>(X3) Date Survey Completed</b>  08/30/2023
<b>Name of Provider or Supplier</b>  Medplus Urgent Clinic, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel records since 2/6/2022 and an interview with testing personnel #1/general supervisor (TP/GS) at 5:00 p.m. on 8/30/2023, the laboratory failed to follow written policies to assess the technical consultant (TS) and technical supervisor (TS) competency annually. The technical consultant/technical supervisor competency evaluation had not been performed by the laboratory director since 8/30/22. Findings include: 1. There was no documented competency evaluation available for review on the TC or TS. 2. Laboratory policy stated that the TC and TS would be evaluated at least annually. 3. TP #1 confirmed in an interview at 5:00 p.m. on 8/30/2023 that the laboratory failed to follow policies to assess general supervisor and technical consultant competency.</p>
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii)</p>

Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the Medonic M Series hematology analyzer records including quality control, maintenance, and calibration records from 2/1/2022 through 8/30/2023 and confirmation with testing personnel (TP) #1 (as listed on the Centers for Medicare and Medicaid Services 209 Personnel form) at 10:00 a.m. on 6/14/2023, the laboratory failed to calibrate the CBC (complete blood count) performed on the Medonic M Series every 6 months as required by the written laboratory procedure manual and instrument manufacturer for 1 of 3 calibrations due. Findings include: 1. Review of the Medonic M Series calibration records revealed calibration was performed on 12/6/2021, 6/1/2022, 4/12/2023 and 5/18/2023. 2. The manufacturer requires that the Medonic M series be calibrated every 6 months. 3. The time frame between the calibration on 6/1/2022 and 4/12/2023 exceeded the required 6 month calibration. 4. TP #1 confirmed in an interview at 10:00 a.m. on 8/30/2023 that CBC calibrations were not performed every 6 months for 1 of 3 calibrations required between 2/1/2022 and 8/30/2023.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on surveyor review of Medonic M Series hematology analyzer calibrations from 2/1/2022 through 8/30/2023, and interview with TP#1 at 3:00 p.m. on 8/30/2023, the technical consultant (TC) failed to document review for 2 of 3 Medonic calibrations performed for the evaluation of the competency of the staff. Findings Include: 1. Review of Medonic M Series calibrations from 2/6/2022 through 8/30/2023 revealed no documentation of review by the TC for 2 of 3 calibrations. 2. TP #1 confirmed in an interview at 3:00 p.m. on 8/30/2023 that Medonic M Series calibrations performed on 4/12/2023 and 5/18/2023 were not documented as reviewed by the TC.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory personnel records since 2/6/2022, including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel competency evaluations, and interview with testing personnel (TP) #1 at 5:00 p.m. on 8/30/2023, the technical consultant (TC) failed to evaluate and document

the performance of testing personnel TP #6 and TP #7 (2 of 6 new TP since 2/6/2022) at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the laboratory personnel records indicated that TP #6 and TP#7 were initially trained on 8/31/2022 and 8/2/2022. 2. There was no 6-month competency evaluation available for review on TP #6 (due in January 2023) and for TP #7 (due in January 2023). 3. TP #1 confirmed in an interview at 5:00 p.m. on 8/30/2023 that there were no 6-month competency evaluations documented as performed on TP #6 or TP #7 during their first year of performing moderate complexity testing. 4. The TC failed to document 6-month competency evaluations on 2 of 6 new testing personnel.