Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1026761	02/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Medical Care Pllc	401 E Main Street, Johnson City, TN	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory director/designee failed to sign three of nine attestation statements from 2024. The findings include: 1. A review of the laboratory's 2024 API proficiency testing attestation statements revealed the laboratory director/designee failed to sign the attestation statements for the following: - Hematology 2024 third event - Chemistry 2024 third event - Microbiology 2024 third event 2. An interview with the laboratory lead on 02.14.2025 at 12:30 p.m. confirmed the above survey findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to retain all records for nine of nine proficiency testing events in 2023. The findings include: 1. A review of the laboratory's API PT records revealed the following: - No records were available for the laboratory's 2023 Hematology first, second, or third events. - No

	records were available for the laboratory's 2023 Chemistry first, second, or third events. - No records were available for the laboratory's 2023 Microbiology first, second, or third events. 2. An interview with the laboratory lead on 02.14.2025 at 8:45 a.m. confirmed the above survey findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report form (CMS-209), a review of laboratory policy, testing personnel (TP) records, and staff interview, the laboratory failed to follow the "Laboratory Competency" policy for evaluating annual competency for two of eight moderately complex testing personnel performing Potassium Hydroxide (KOH) and Direct Wet Mount patient testing in 2024. The findings include: 1. A review of the CMS-209 revealed eight persons (TP1, TP2, TP3, TP4, TP5, TP6, TP7 and TP8) who perform moderately complex patient testing. 2. A review of the "Laboratory Competency" policy revealed the following statement: -"Documentation of competency for new staff member will be maintained at 30, 60, 90 days and annually thereafter in the employees' folder." 3. A review of the laboratory's testing personnel records revealed no documentation of 2024 annual competency assessments for moderately complex testing personnel TP7 and TP8 that performed KOH and Direct Wet Mount patient testing in 2024. 4. An interview with the laboratory lead on 02.14.2025 at 12:30 p.m. confirmed the above survey findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 observation of the laboratory, review of laboratory procedures, request for

	calibration verification records and staff interview, the laboratory failed to perform calibration verification on the Beckman Coulter AU480 and the Abbott Architect i1000 in 2024. The findings include: 1. Observation of the laboratory on 02.14.2025 at 10:05 am revealed the Beckman Coulter AU480 (serial # 2014093539) and the Abbott Architect i1000 (serial # ISR51897) in use for patient testing for serum chemistry and endocrinology. 2. Review of the laboratory "Calibration Testing" procedure revealed the following frequency for linearity (calibration verification): -Beckman Coulter AU480-every 6 months -Abbott Architect i1000- every 6 months 3. Request for calibration verification records for the Beckman Coulter AU480 and the Abbott Architect i1000 revealed no calibration verification studies had been performed in 2024. 4. An interview with the laboratory lead on 02.14.2025 at 12:30 p.m. confirmed the findings.