Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0991846	07/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Medical Care, Inc	1402 Wayne Memorial Drive, Goldsboro, NC	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on deficiency cited at D5423 and review of laboratory procedure manual 7/27 /23, the laboratory failed to establish a policy for specimen storage and stability requirements for the toxicology testing performed on the Pictus 500 analyzer. Findings: The laboratory failed to verify specimen storage and stability requirements. See D5423. Review of laboratory procedure manual revealed no policy or procedure for specimen storage and stability.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with laboratory director (LD) 7/27/23, the LD failed to approve, sign and date all laboratory procedures before they assumed the role in January of 2023. Findings: Review of laboratory procedure manual revealed no documentation the current LD had

	approved, signed and dated the laboratory procedures and policies before assuming the role of LD in January of 2023. Interview with LD at approximately 10:30 a.m. and 3:15 p.m. confirmed they assumed the role of LD in January of 2023. LD also confirmed they had not approved, signed and dated all laboratory procedures.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of manufacturer package inserts, off-site review of Federal Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) database and review of verification of performance records for the Pictus 500 analyzer 7/27/23, the laboratory failed to verify the specimen storage and stability requirements for 14 of 15 toxicology analytes tested on the Pictus 500 analyzer since testing began in July of 2021, a period of approximately 2 years. Findings: Review of toxicology reagent package inserts and off-site review of the FDA CLIA database revealed the following toxicology analytes are not categorized by the FDA for use on the Pictus 500 analyzer: 1. CEDIA Heroin Metabolite (6-AM) reagent. 2. DRI Amphetamine (AMP) reagent. 3. DRI Benzodiazepine (BENZ) reagent. 4. CEDIA Buprenorphine (BUP) reagent. 5. DRI Cocaine (COC) reagent. 6. DRI Ecstasy (XTC) reagent. 7. DRI Ethyl Glucuronide (ETG) reagent. 8. DRI Ethyl Alcohol (ETOH) reagent. 9. DRI Fentanyl (FEN) reagent, 10. DRI Methadone (MTD) reagent. 11. DRI Opiate (OPI) reagent. 12. DRI Oxycodone (OXY) reagent. 13. DRI Phencyclidine (PCP) reagent. 14. DRI Cannabinoid (THC) reagent. Review of verification of performance records for the Pictus 500 revealed no documentation the laboratory had verified the specimen storage and stability requirements for 14 of 15 analytes not categorized by the FDA (see above list of analytes).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Pictus 500 analyzer operator manual, review of 2021, 2022, and 2023 maintenance records, the absence of records, and interview with LD 7/27/23, the laboratory failed to perform and/or document all manufacturer's specified daily, weekly, and monthly maintenance for the Pictus 500 analyzer for 2021, 2022 and

	January thru June of 2023. 1. The laboratory failed to perform and/or document all daily maintenance tasks for 7 of 12 months in 2022, and 3 of 6 months in 2023. Findings: Review of operator's manual for the Pictus 500 revealed the following daily maintenance tasks, section "7.6 Daily Task: 1. Probe Tip Inspection. 2. Fresh Control or Serum at ISE Prime Position (For instruments having ISE 7.3.1). 3. Refill System Wash Bottle. 4. Empty Waste Bottle. 5. System Flush 6. Cuvette Water Blank .". Review of daily maintenance records for the Pictus 500 revealed the following dates in which all tasks for daily maintenance were not documented: March 2022: Maintenance Log missing, LD unable to locate. April 2022: 4/29/22 and 4/30/22. May 2022: 5/24/22 thru 5/27/22. June 2022: 6/5/22, 6/6/22, 6/13/22, 6/15/22, 6/16/22, 6/28 /22 thru 6/30/22. August 2022: 8/1/22, 8/6/22, 8/16/22, thru 8/18/22, and 8/27/22. September 2022: 9/3/22. October 2022: 10/8/22 and 10/15/22. January 2023: 1/14/23, 1/15/23, 1/21/23 thru 1/23/23 and 1/27/23. February 2023: 2/3/23, 2/10/23, 2/11/23, 2 /17/23 and 2/19/23. March 2023: 3/3/23. 2. The laboratory failed to perform and/or document all weekly maintenance tasks for 11 of 12 months in 2021, 12 of 12 months in 2022, and 3 of 6 months in 2023. Findings: Review of operator's manual for the Pictus 500 revealed the following weekly maintenance tasks, section "7.6 Weekly Task: 1. Manual Tip Clean. 2. Check & Replace if needed, diluents and cleaning solutions at reagent tray. 3. Service Backup. 4. Intensive Cuvette Cleaning.". Review of weekly maintenance records for the Pictus 500 revealed the following number of weeks in which weekly maintenance was not performed and/or documented each month: January 2021: 2 of 4 weeks. February 2021: 1 of 4 weeks. April 2021: 2 of 4 weeks. May 2021: 1 of 4 weeks. June 2021: 4 of 4 weeks. July 2021: 1 of 4 weeks. August 2021: 1 of 4 weeks. September 2021: 3 of 4 weeks. October 2021: 3 of 4 weeks. November 2021: 2 of 4 weeks. December 2021: 1 of 4 weeks. January 2022: 1 of 4 weeks. February 2022: 2 of 4 weeks. March 2022: Maintenance Log missing for March 2022; LD unable to locate; 4 of 4 weeks. April 2022: 4 of 4 weeks. May 2022: 4 of 4 weeks. June 2022: 4 of 4 weeks. July 2022: 4 of 4 weeks; August 2022: week one, tasks incomplete; no tasks completed for remaining 3 weeks September 2022: week one missed; tasks incomplete for week 2 and 3 October 2022: 2 of 4 weeks. November 2022: 3 of 4 weeks. December 2022: 3 of 4 weeks. January 2023: 1 of 4 weeks. February 2023: 4 of 4 weeks. March 2023: 3 of 4 weeks. 3. The laboratory failed to perform and/or document monthly maintenance on the Pictus 500 from January of 2021 thru June of 2023, a period of approximately 30 months. Findings: Review of operator's manual for the Pictus 500 revealed the following monthly maintenance tasks; Section "7.6 Monthly Task: 1. Photometer Calibration. 2. Washer Volume Calibration. 3. Clean System Bottles. 4. Intensive Washer Cleaning.". Review of 2021, 2022 and 2023 maintenance records for the Pictus 500 revealed no documentation of the performance of monthly maintenance. During interview with LD at approximately 1:37 p.m., LD stated they were not aware the current maintenance log in use by the laboratory did not reflect all the required maintenance for the Pictus 500.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory performance verification records for the Pictus 500 analyzer, review of random patient reports and interview with LD 7/27/23, the laboratory failed to ensure patient test reports included only the qualitative value for the toxicology testing performed. Findings: Review of laboratory performance verification records revealed the laboratory verified the performance of the toxicology testing for qualitative testing only. Review of random patient test reports revealed qualitative and quantitative toxicology test results for all analytes tested. The following random patient test reports were reviewed: a. Sample Id 7773, Patient Id 0288 completed 2/24/23. b. Sample Id 8082, Patient Id 0444 completed 3/18/23. Interview with LD at approximately 1:00 p.m. confirmed patient test reports included quantitative test results and also confirmed the laboratory had only verified the performance of qualitative values for the toxicology testing performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of toxicology reagent package inserts, off-site review of Federal Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) database, review of LD qualification documents and interview with LD 7/27/23, the laboratory failed to ensure the LD met the qualification requirements for performing high complexity testing. Findings: See D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and

	continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of manufacturer package inserts, review of Federal Drug Administation (FDA) Clinical Laboratory Improvement Amendments (CLIA) database, laboratory director (LD) qualification review and interview with LD 7/27 /23, the laboratory failed to ensure the LD met the qualification requirements for performing high complexity testing. Findings: The LD serves as the general supervisor (GS), technical supervisor(TS) and testing personnel (TP). The LD began employment as TP in March of 2022 and assumed the role of LD in January of 2023 when the previous LD resigned. Review of toxicology reagent package inserts and off-site review of the FDA CLIA database revealed the following toxicology analytes are not categorized by the FDA for use on the Pictus 500 analyzer. 1. CEDIA Heroin Metabolite (6-AM) reagent. 2. DRI Amphetamine (AMP) reagent. 3. DRI Benzodiazepine (BENZ) reagent. 4. CEDIA Buprenorphine (BUP) reagent. 5. DRI Cocaine (COC) reagent. 6. DRI Ecstasy (XTC) reagent. 7. DRI Ethyl Glucuronide (ETG) reagent. 8. DRI Ethyl Alcohol (ETOH) reagent. 9. DRI Fentanyl (FEN) reagent, 10. DRI Methadone (MTD) reagent. 11. DRI Opiate (OPI) reagent. 12. DRI Oxycodone (OXY) reagent. 13. DRI Phencyclidine (PCP) reagent. 14. DRI Cannabinoid (THC) reagent. Review of LD qualification documents revealed a bachelor's degree in medical technology. A bachelor's degree in medical technology fails to meet the LD qualification requirements for high complexity testing. Interview with LD at approximately 11:50 a.m. confirmed they had a bachelor's degree in medical technology only. The LD stated they were unaware the toxicology testing performed on the Pictus 500 was high complexity. She also stated she was informed by the previous LD she would qualify as the LD for the facility.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on deficiencies cited at D5311 and D5423, review of CMS (Center for Medicare /Medicaid Services) 116 form's annual test volume submitted at time of survey and LD interview 7/27/23, the LD failed to ensure TP performed test methods on the Pictus 500 that provided accurate and reliable results, approximately 540 patient samples were tested after being stored in a freezer 2/17/22 thru 5/10/22. Findings:

	Based on deficiencies cited at D5311 and D5423, the laboratory failed to have a policy or procedure for specimen storage and stability and failed to establish and verify specimen storage and stability requirements for the high complexity testing performed on the Pictus 500. Review of CMS 116 annual test volume revealed the laboratory performs approximately 180 toxicology drug panels a month on the Pictus 500 analyzer. Approximately 540 patient samples were tested after being stored in a freezer 2/17/22 thru 5/10/22. During interview with LD at approximately 1:30 p.m., the LD stated no testing was performed from 2/17/22 thru 5/10/22 and patient specimens collected from 2/17/22 thru 5/10/22 were frozen until testing resumed on 5 /10/22, a period of approximately 3 months. LD also confirmed the annual test volume on the CMS 116 was correct.