Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1026761	07/26/2023
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) 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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, determined the laboratory director failed to sign the attestation sheets for 6 of 6 PT events for 2022. The findings include: 1. Request of the laboratory's PT records revealed the following: -Attestation pages not signed by the laboratory director for the following: Chemistry 2022 event one, two, and three Hematology/Coagulation 2022 event one, two, and three 2. Interview with the lead testing person (TP#1) at approximately 1:00 p.m. on 07.26.2023 confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Citation 1 Based on review of the laboratory's procedure manual, review of the laboratory's monthly quality control reports and staff interview, determined that the laboratory failed to follow its' own written policy for reviewing quality issues monthly

	for 17 of 17 months from January 2022 through May 2023. The findings include: 1. Review of the laboratory's procedure manual under the section titled, "Quality Improvement Plan" revealed the following statement, "Quality issues will be reviewed monthly. Records of any problems identified, actions taken, and results of such actions will be maintained, evaluated by the Medical Director and shared will all staff members on a regular basis." 2. Review of the laboratory's monthly quality control reports for January 2022 through May 2023 revealed no documented laboratory director/medical director review and/or signature for 17 of 17 months. 3. Interview with the lead testing person (TP#1) at approximately 1:00 p.m. on 07.26.2023 confirmed the laboratory failed to follow its' own written policy for reviewing quality issues monthly for 17 of 17 months from January 2022 through May 2023. Citation 2 Based on direct observation, document request, and staff interview, determined the laboratory failed to have a procedure for performing KOH/Wet Prep patient testing for 19 of 19 months, from January 2022 through the survey date of 07.26.2023 The findings include: 1. Direct observation of the "nurse's station" beside the laboratory at approximately 9:45 a.m. on 07.26.2023 revealed an OMAX microscope, EDM 3 Solutions Potassium Hydroxide 10% solution, and NaCl solution on the counter. 2. Request for the procedure for performing KOH/Wet Prep testing revealed there was no procedure available. 3. Interview with the lead testing person (TP#1) at approximately 1:00 p.m. on 07.26.2023 confirmed the laboratory did not have a procedure for performing KOH/Wet Prep testing for 19 of 19 months, from January 2022 through the survey date of 07.26.2023. Word Key: NaCl= Sodium chloride
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, record request, review of instrument reference guide, and staff interview, determined the laboratory failed to perform quality control (QC) each day of patient testing or develop and implement an Individualized Quality Control Plan (IQCP) for Chlamydia, Neisseria, and Trichomonas for patient testing on the Cepheid GeneXpert after 07.06.2022 through the survey date of 07.26.2023 The findings include: 1. Direct observation of the laboratory at approximately 1:00 p.m. on 07.26.2023 revealed a Cepheid GeneXpert in use for patient testing. 2. Request for QC for Chlamydia, Neisseria, and Trichomonas on the Cepheid GeneXpert revealed none had been performed since 07.06.2022 with 737 patient results from 07.06.2023 through the survey date of 07.26.2023. 3. Review of the GeneXpert Reference guide revealed, "Positive and negative external controls should be used in accordance with local, state, and federal accrediting organizations' requirements as applicable." 4. No IQCP for Chlamydia, Neisseria, and Trichomonas on the Cepheid GeneXpert was available for review at the time of survey on 07.26.2023. 5. Interview on at approximately 11:00 a.m on 07.26.2023 with the lead testing persone (TP#1) confirmed the laboratory did not perform QC daily and did not have an IQCP in place

	for Chlamydia, Neisseria, and Trichomonas for patient testing on the Cepheid GeneXpert after 07.06.2022 through the survey date of 07.26.2023.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, determined the laboratory director failed to ensure proficiency testing results were reviewed for 6 of 6 proficiency testing performance evaluation reports in 2022. The findings include: 1. Review of the laboratory's PT records revealed the following: -Performance evaluation reports not reviewed/signed by laboratory director for the following: Chemistry 2022 event one, two, and three Hematology/Coagulation 2022 event one, two, and three 2. Interview with the lead testing person (TP#1) at approximately 1:00 p.m. on 07.26.2023 confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), request for testing personnel training /competency records, record review, and staff interview, determined the laboratory director failed to participate in the training of two of seven testing personnel for performance of KOH/Wet prep prior to patient testing that began on 01.01.2022 with approximately 312 patient tests reported between 01.01.2022 and 07.26.2023. The findings include: 1. Review of the Form CMS-209 revealed two testing personnel (TP#6 & TP#7) who perform KOH/Wet preps for patient testing. 2. Request for testing personnel training records revealed no evidence the lab director participated in the training process for KOH/Wet Prep testing for two of two (TP#6 & TP#7) testing personnel prior to patient testing that began on 01.01.2022. 3. Interview with the lead testing person (TP#1) at approximately 1:00 p.m. on 07.26.2023 and email communication on 08.03.2023 with the lead testing person (TP#1), confirmed no

	evidence available to show the laboratory director participated in the training process for two of seven testing personnel for performance of KOH/Wet Prep prior to patient testing that began on 01.01.2022 with approximatley 312 patient tests reported between 01.01.2022 and 07.26.2023.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on direct observation, document request, and staff interview, determined the laboratory failed to have a procedure for performing KOH/Wet Prep patient testing for 19 of 19 months, from January 2022 through the survey date of 07.26.2023 The findings include: 1. Direct observation of the "nurse's station" beside the laboratory at approximately 9:45 a.m. on 07.26.2023 revealed an OMAX microscope, EDM 3 Solutions Potassium Hydroxide 10% solution, and NaCl solution on the counter. 2. Request for the procedure for performing KOH/Wet Prep testing revealed there was no procedure available. 3. Interview with the lead testing person (TP#1) at approximately 1:00 p.m. on 07.26.2023 confirmed the laboratory did not have a procedure for performing KOH/Wet Prep testing for 19 of 19 months, from January 2022 through the survey date of 07.26.2023. Word Key: NaCl= Sodium chloride