Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0913549	06/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Quadmed Clinic West Allis	555 S 108th St, West Allis, WI	

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
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 surveyor review of laboratory quality control (QC) and Individualized Quality Control Plan (IQCP) records and interview with the laboratory director, the laboratory did not perform two levels of quality control on each day of patient testing and had not developed an IQCP for the Cepheid Gene Xpert analyzer for two of two moderate complexity tests. Findings include: 1. Review of QC records for the Cepheid Gene Xpert test showed QC was performed each new lot or shipment. 2. Review of IQCP records showed no evidence of an IQCP specific for the Cepheid Gene Xpert testing for Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) and Trichomonas vaginalis (TV) test. 3. Interview with the laboratory director on June 30, 2023, at 1:35 PM confirmed the laboratory did not perform two levels of quality control on each day of patient testing and had not developed an IQCP for the Cepheid Gene Xpert CT /NG and TV tests.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory

	performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on survey review of a patient's Basic Metabolic Panel (BMP) test report and laboratory procedures and interview with the laboratory director, the reference ranges shown on the patient report was not the same as the approved reference ranges for four of six chemistry analytes reviewed. Findings include: 1. Review of the reference range of the BMP test report from October 13, 2022, in the electronic medical record (EMR) for an adult male showed the following expected ranges: Analyte/Reference range Sodium/134-143 milli moles/Liter (mmol/L) Potassium/3.5-5.0 mmol/L Chloride/99-109 mmol/L Blood Urea Nitrogen/8-23 milligrams/deciliter (mg/dL) Creatinine/0.6-1.21 mg/dL Calcium/8.3-10.6 mg/dL 2. Review of the individual analyte Abbott Architect 4100 chemistry procedures showed the approved reference ranges for an adult male are: Analyte/Reference range Sodium/136-145 mol/L Potassium/3.5-5.1 mmol/L Chloride/98-107 mmol/L Blood Urea Nitrogen/8-23 mg /dL Creatinine/0.72-1.25 mg/dL Calcium/8.3-10.6 mg/dL Further review showed the sodium, potassium, chloride and creatinine reference ranges in the procedures did not match the patient's test report. 3. Interview with the laboratory director on June 30, 2023, at 2:50 PM confirmed the reference ranges in the EMR were not consistent with the approved reference ranges in the procedures.