Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0706101	10/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Metro West Ambulance	5475 Ne Dawson Creek Drive, Hillsboro, OR	

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) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of the laboratory's Individual Quality Control Procedures (IQCP) and interview with testing personnel (TP), the laboratory failed to follow its written Quality Control Plan (QCP) for the iSTAT analyzer. Findings included: 1. Review of the laboratory's iSTAT IQCP revealed that reagent lot checks are required for each new reagent lot and each new shipment of reagent prior to use in patient testing. 2. Upon request, the laboratory was unable to provide documentation demonstrating that the required iSTAT reagent lot checks had been performed. 3. Interview with TP #7 and TP #9 at 10:30 am on 10/07/2026 confirmed there was no documentation of iSTAT reagent lot checks. 4. The laboratory performs 16,200 iSTAT tests annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in

	493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individual Quality Control Procedures (IQCP) and interview with testing personnel (TP), the laboratory failed to document verification that each new lot number of iSTAT reagent performed as expected prior to use in patient testing. Findings include: 1. Upon request, the laboratory was unable to provide documentation of verification checks for new iSTAT reagent lots received during 2025 and 2026 to date. 2. Interview with TP #7 and TP #9 at 10:30 am on 10/07/2026 confirmed there was no documentation of iSTAT reagent lot checks. 3. The laboratory performs 16,200 iSTAT tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interviews with testing personnel (TP), the laboratory failed to establish and implement a procedure to evaluate testing when the same analyte is tested on multiple analyzers twice a year. Findings include: 1. The laboratory had eight (8) iSTAT analyzers in use that use the CHEM8 reagent cartridge. 2. Upon request, the laboratory was unable to provide documentation of test comparison studies performed among the iSTAT analyzers during 2025 and 2026 to date. 3. Upon request, the laboratory was unable to provide a written policy addressing the comparison of test results for analytes that are tested on multiple analyzers. 4. Interview with TP #7 and TP #9 at 11:00 am on 10/07/2026 confirmed there was no policy on comparison of test results for analytes that are tested on multiple analyzers. 4. The laboratory performs 16,200 iSTAT tests annually.