

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0983584	(X3) Date Survey Completed 06/08/2026
Name of Provider or Supplier Med Trans Corp DbA Airlink Critical Care	Street Address, City, State 2500 Ne Neff Dr, Bend, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Abbott iStat System Verification analysis, performed by St. Charles hospital laboratory staff from 10/1/2009 through 11/12/2009 and interview with the Technical Consultant (TC), the laboratory failed to ensure the three (3) iStat instruments in use, were verified for performance before patient test results were reported. Findings include: 1. Upon receipt of the written iStat System Verification analysis, performed 10/01/2009 through 11/12/2009, it was noted that there were only two (2) analyzers involved in the study, not three (3). 2. The serial numbers for two (2) iStat analyzers in the verification study were listed as #333250 and #306269. 3. The serial numbers of the iStat analyzers reported to be in use at time of survey were #313383, #383188 and #434509. 4. The TC confirmed by email 06/30/2026 that the iStat verification performed from 10/01/2009 - 11/12/2009 was the sole verification analysis for the iStat instruments. 5. The laboratory performs 1100 tests using the iStat analyzers 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 laboratory records and interview with the Technical Consultant (TC), the laboratory failed to perform bi-annual test correlation studies on any of the three (3) Abbott iStat analyzers currently in use. Findings include: 1. Upon request for twice a year comparison studies for the analytes performed on the iStat analyzers, none could be produced. 2. Email with the TC confirmed that they have never performed bi-annual correlation studies on the iStat analyzers. 3. The laboratory performs 1100 tests using the iStat analyzers annually.