Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2012555	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mizzou Urgent Care - Mexico	3626 South Clark Street Suite C, Mexico, MO	

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) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 performance verification procedure for the iStat analyzer, patient results and interview with the technical consultant (TC), the laboratory failed to verify the manufacturer's reference intervals (normal ranges) prior to reporting patient test results. Findings: 1. Review of the performance specifications for the iStat analyzer showed the laboratory failed to verify that the manufacture's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: glucose, urea nitrogen, sodium, chloride, potassium, ionized calcium, total carbon dioxide, creatinine and troponin. 2. . Review of patient results showed the laboratory performed 537 troponin I and 1038 of the following analytes; glucose, urea nitrogen, sodium, chloride, potassium, ionied calcium, total carbon dioxide, creatinine from August 6, 2023 to date September 21, 2024. 3. Interview with the TC on February 21, 2024 at 10:30 AM confirmed the laboratory failed to verify the manufacturer's reference intervals prior to reporting patient results.