Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652497	06/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Benefis Health System West Campus Lab	500 15th Avenue South, Great Falls, MT	

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 record review, patient results reports, and interview with the technical consultant (TC) #1, the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for CG8+ cartridge performed on the i-STAT analyzer. Findings: 1. Review patient results reports for i-STAT CG8+ (#0702:PC00069R) listed reference ranges for the following analytes: Glucose, Sodium, Potassium, Ionized Calcium, TCO2, Hemoglobin, Hematocrit, pH, PO2, PCO2, HCO3, Base Excess, O2 saturation, and BiCarb. 2. No patient population studies to support the reference ranges listed in the i-STAT CG8+ patient results report were available for review. 3. Interview with the TC #1 on June 23, 2022, at 10:24 AM, confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the i-STAT CG8+ cartridge.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient results reports and interview with the Testing Consultant (TC) # 1, the laboratory failed to list the name and address of the testing laboratory and include the normal reference ranges for three out of thirteen CG8+ analytes. Findings: 1. Review patient results reports for i-STAT CG8+ (# 0702: PC00069R) lacked the testing facility's name, address, correct CLIA ID #, and three out of thirteen CG8+ analytes listed on the report. 2. Interview with TC # 1 on June 23, 2022, at 11: 30 AM, confirmed these results.