Statement of Deficiencies

	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	46D2146703	08/22/2018

Name of Provider or Supplier	Street Address, City, State
Intermountain Heber Instacare	1485 South Hwy 40 Ste H, Heber, UT

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 Sysmex PocH-100i instrument verification records review, lack of documentation, and interview with staff, the laboratory failed to demonstrate they could obtain the manufacturer's performance specifications for the reportable range for 5 of 5 complete blood cell count (CBC) parameters (red blood cell {RBC}, white blood cell {WBC}, platelets {PLT}, hemoglobin {HGB}, and mean corpuscular volume {MCV}). Findings include: 1. Instrument verification records consisted of instrument calibration records and failed to include values at the upper and lower ends of the manufacturer's reportable range for RBC, WBC, PLT, HGB, and MCV 2. The technical consultant stated on 08/22/2018 at approximately 2:00 p.m. the PocH-100i had been relocated from another laboratory and she did not realize performance specification verification needed to be performed in their laboratory.