Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2093225	04/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Colorado Springs Rrl - Quest Diagnostics	2141 Academy Cir Suite 105, Colorado Springs, CO	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the operator's manual, maintenance records, and staff interview, the laboratory failed to ensure the humidity in the laboratory met the manufacturer's operating conditions for the Sysmex 1000i hematology analyzer and the Sysmex CA600 coagulation analyzer during the first three months of 2019. Approximately 90 patient specimens had been tested and reported. Findings include: a. The manufacturer requires an operating environment of 30-85% relative humidity for the Sysmex 1000i and the Sysmex CA600 analyzers. b. Maintenance records for 2019 showed that the humidity in the laboratory was below 30% for a total of 31 of 63 days of testing (Jan. =14/22 days, Feb.=14/20 days, Mar.=3/21 days). c. On 4-9-19 at around 11:00 a.m., the laboratory director stated that they were aware that the humidity was outside the acceptable range for the Sysmex analyzers, and stated that they were gathering data to extend the acceptable humidity range for the laboratory. d. On 4-9-19 at around 11:00 a.m., the laboratory director confirmed the laboratory had not ensured a testing environment of at least 30% humidity as required by the Sysmex manufacturer and federal CLIA regulations.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the operator's manual, laboratory policy, maintenance records, and staff interview, the laboratory failed in 2019 to take corrective actions on 31 of 63 days of testing from January through March when the ambient humidity within the laboratory was outside of the acceptable range for the Sysmex 1000i and the Sysmex CA600 analyzers. Approximately 90 patient specimens had been tested and reported. Findings include: a. The manufacturer requires an operating environment of 30-85% relative humidity for the Sysmex 1000i and the Sysmex CA600. b. Laboratory policy stated, "If the humidity is outside the specified target range, document corrective actions on the humidity monitoring log." c. Maintenance records for 2019 showed that the humidity in the laboratory was below 30% for 31 of 63 days of testing (Jan.=14/22 days, Feb.=14/20 days, Mar.=3/21 days). d. On 4-9-19 at about 11:00 a.m., the laboratory director stated they were aware the humidity level in the laboratory had been outside of the acceptable range for the Sysmex analyzers, but they took no corrective action. e. On 4-9-19 at about 11:00 a.m., the laboratory director confirmed they had not followed their laboratory policy to take and document corrective actions when the humidity was outside the acceptable range as required by their policy and the federal CLIA regulations.