Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 06D2097444	**(X3) Date Survey Completed** 04/17/2018
Name of Provider or Supplier Insight Laboratories	**Street Address, City, State** 10841 South Crossroads Drive, Parker, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy for thermometer certification, the direct observation of two thermometers, a lack of calibration records, and staff interview, the laboratory failed in 2016 and 2017 to follow their written policy to annually perform and document the calibration of two thermometers used in the laboratory. Findings include: a. The laboratory's policy states, "Once a year, all of the thrermometers are checked at operating temperatures against one of the NIST-traceable thermometers" and, "Annual Thermometer Calibration Reports for NIST-traceable thermometers are stored in the Thermometers Calibration Certificates Notebook." b. No calibration date was indicated on thermometers #H1 and #H2. c. No operator's manual or package insert was found for the thermometers. d. No documentation existed to show the thermometers had been calibrated each year. e. Staff stated they were unaware of any calibration performed on the thermometers and confirmed no calibration documentation for the thermometers could be found in the laboratory.
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 2017 to take corrective actions each day of testing when the ambient humidity within the laboratory was outside of the acceptable range for the Beckman Coulter AU400 chemistry analyzer. Findings include: a. The Beckman Coulter operator's manual stated the humidity in the laboratory for testing must be between 40-80% relative humidity (RH). b. The laboratory's policy stated that the humidity range for the AU640 should be 30-80% RH. c. Maintenance log sheets showed an acceptable range for the ambient humidity as "greater than 30%." c. Maintenance records for 2017 showed no corrective action was taken when the humidity in the laboratory was below the acceptable range on 194 of 253 days of testing from January through December (Jan=21 days, Feb=20, Mar=17, Apr=20, May=11, June=18, Jul=7, Aug=7, Sep=17, Oct=16, Nov=20, Dec=20). d. Staff stated they were unaware that corrective actions needed to be taken, and confirmed no corrective action had been taken any day the humidity in the laboratory was outside of the manufacturer's requirements for the testing environment as required by the federal CLIA regulation.