Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2112109	(X3) Date Survey Completed 08/22/2018
Name of Provider or Supplier Pyxant Labs, Inc	**Street Address, City, State** 4720 Forge Road, Suite 108, 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 laboratory director interview, the laboratory failed for three months in 2018 to ensure the humidity in the laboratory met the manufacturer's required operating conditions for the Beckman Coulter AU400 chemistry analyzer and 4,876 patient specimens were tested. Findings include: a. The laboratory performs drug screen testing on patient urine and oral fluid specimens using the Beckman Coulter AU400 chemistry analyzer. b. The operator's manual for the Beckman Coulter AU400 chemistry analyzer stated the relative humidity in the laboratory must be between 40 and 80%. c. Maintenance log sheets showed the room humidity was less than 40% each day of patient testing for three months in 2018 (2-1-18 through 5-1-18). d. On 8-22-18 at around 12 p.m., the laboratory director stated they were aware of the manufacturer's high humidity requirements for the chemistry analyzer, and stated it's not possible to obtain a 40% humidity level in a Colorado laboratory and so they did nothing to mitigate the unacceptable humidity levels in their laboratory. e. On 8-22-18 at around 12 p.m., the laboratory director confirmed the laboratory had not ensured a testing environment of at least 40% relative humidity each day of patient testing as required by the operator's manual for the Beckman Coulter AU400 chemistry analyzer.

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 a review of one random patient test report and staff interview, the laboratory failed to include on the patient report the facility address of the laboratory where the testing was performed. Findings include: a. The laboratory's final patient report contained the facility name but did not indicate the address of the laboratory location where the testing had been performed. b. On 8-22-18 at about 1 p.m., the laboratory director and the technical supervisor stated they were unaware the laboratory address was not included on the report, and confirmed the laboratory address was not indicated anywhere on the final patient report as required by the federal CLIA regulations.