

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2065692	(X3) Date Survey Completed 08/29/2018
Name of Provider or Supplier Advanced Pain Diagnostic & Solutions	Street Address, City, State 729 Sunrise Ave, Ste 602, Roseville, CA	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the digital thermometers used in the laboratory, review of the temperature records, and interview with the testing personnel (TP), it was determined that the laboratory failed to familiarize the features of the digital thermometers used to monitor and documented properly for proper storage of the laboratory reagents, supplies including control and calibrator materials. The findings included: a. At the time of survey (08/29/18 @ 11 AM), observed a digital thermometer for a freezer which is used to hold the urine samples before they are ready for urine drug screen testing. b. The laboratory stated that the optimal acceptable temperature to store the urine samples properly is below -20 oC. c. The digital temperature at the time (@ 11 AM) indicated that it was -19 oC, which was outside of the acceptable range. d. Interview of TP about the features and functions of this digital thermometer, the TP who was assigned to read and document the temperature conditions showed lack of knowledge of the digital thermometer's functions. e. Further discussion and observations of the digital thermometers, the laboratory failed to set up the acceptable temperature ranges correctly for both refrigerator and freezer digital thermometers. f. The laboratory intentionally switched the built-in "Alarm" to "Off" position to avoid its noise, when the temperature reach outside of the acceptable ranges.</p>

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory supplies including the calibrator and control materials in the refrigerator, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to label the supplies after opened to indicate the storage requirements and preparation and expiration date to ensure the strength, concentration as appropriate. The findings included: a. The laboratory performed urine drug screen and reported "Positive" or "Negative" results for a total of 10 drugs analyze including but are not limited to the following analyte: Buprenorphine, Oxycodone, Cannabinoids. Opiates. b. Observed the calibrator and control materials in a refrigerator, calibrators for Buprenorphine and Oxycodone were not labeled with open date and expiration date. Neither the controls materials were not labeled with opened date and expiration date.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory operations, and interview with the laboratory testing person (TP), it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included See D- 5413 and D-5415