

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2219608	(X3) Date Survey Completed 07/10/2023
Name of Provider or Supplier San Ysidro Health Urgent Care	Street Address, City, State 333 H St, Ste 2080, Chula Vista, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on touring the laboratory facility, and observed the digital thermometers for a refrigerator and a freezer to store the laboratory supplies including the control materials, and interviewed with the laboratory staff (A&B), it was determined that the laboratory failed to follow the manufacturer's instructions for the digital thermometer that the laboratory selected to assure the temperatures were maintained and within the laboratory established acceptable temperature ranges, and provide test results within the laboratory's stated performance specifications for each test system. The findings included: a. The laboratory failed to train the laboratory personnel to understand the device selected by the laboratory to maintain a proper temperature for storage of the laboratory supplies. b. The laboratory used a digital thermometer, LAB InTemp by Onset, which features "current temperature", "lo/hi" mode for acceptable temperature range, "min/max" mode to indicate a temperature condition in the past (not known exact when), "alarm" to alert the laboratory that any temperature is out of the acceptable range. c. The laboratory staff A, did not know how to set the "acceptable temperature range" for the freezer, the person who knew is on PTO (leave). d. The laboratory staff B, when was asked (7/10/23 @12:29 PM), looked at the digital thermometer for the refrigerator, and saw 3.43/min and 5.74 max, and stated the acceptable temperature range for a refrigerator is 3.43 to 5.74 Celsius. e. The laboratory staff A, replied and corrected the acceptable temperature range for the refrigerator is 2 to 8 Celsius.</p>

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 touring the laboratory facility, and review of the laboratory's "TEMPERATURE LOG", and interview with the laboratory staff (A&B), it was determined that the laboratory failed to define and indicate the "Temp Rang" for both the refrigerator and freezer temperature logs, and failed to consistently record the temperature daily. The findings included: a. The laboratory failed to indicate the acceptable temperature ranges on the "TEMPERATURE LOG" and failed to consistently record daily temperature monitored. b. Review both "TEMPERATURE LOG" (7/10/2023 @ 12:35PM) for the refrigerator and the freezer for the year of 2023 (from January thru December), c. Both LOGs missed the "Temp Range" to indicate the laboratory established acceptable temperature ranges. d. Both LOGs missed 10 temperature records (from January to July 2023) as follows: 2/2/2023, 2/3/2023, 2/11/2023, 3/6/2023, 3/10/2023, 3/11/2023, 3/17/2023, 3/19/2023, 3/21/2023, and 6/2/2023. e. The laboratory failed to monitor and to record daily temperature consistently.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on touring and observed the laboratory facility, review of the laboratory's temperature records, and interview with the laboratory staff (A&B), it was determined that the laboratory director failed to ensure the quality control program is established and maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory director failed to ensure the quality control program is established and maintained to assure the quality of laboratory services provided. b. The laboratory failed to train and follow the manufacturer's instructions to understand the features of the digital thermometer (see D-5411). c. The laboratory failed to indicate the established acceptable temperature ranges for the storage temperature conditions and failed to consistently record daily temperature records see D-5413.