

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1098267	(X3) Date Survey Completed 01/04/2018
Name of Provider or Supplier Omnipathology Solutions	Street Address, City, State 968 S Fair Oaks Ave, Pasadena, 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 review of the refrigerator log for the year 2017, random patient test results and interview with the laboratory director, it was determined that the laboratory failed to follow with the manufacturer's instructions. The findings included: a. The Hologic Aptima manufacturer storage and handling temperature requirements for controls and other reagents stated that: " Aptima control kits are to be stored at 2 to 8 degrees Celsius." b. The laboratory's refrigerator temperature logs have the following entries. 1/ 2017: Temp in Degrees Celsius: 1/4 0 1/5 0 1/11 0 1/12 0 1/16 0 2/2017 2/13 0 2/14 0 2/15 0 2/16 0 3/2017 3/2 0 3/13 0 4/2017 4/6 0 4/7 0 4/8 0 5/2017 5/17 0 5/18 0 6/2017 6/1-6/30 0 7/2017 7/1-7/19 0 8/2017 8/29 0 8/30 0 9/2017 9/7 0 9/18 0 10/2017 10/22 0 10/31 0 11/2017 11/3 0 11/30 0 12/2017 12/8 0 12/12 0 Note: Dates are randomly selected as an example, there are other dates that have fallen outside acceptable ranges. c. For five (5) out of five (5) random patient test results reviewed from 7/27/2016 to 11/2/2017, the laboratory analyzed and reported patient test results that could have been affected by the out of ranges refrigerator temperatures. d. The laboratory director affirmed (1/4/2018, 12N), that the laboratory did not follow the manufacturer's recommended refrigerator temperature requirements.</p>
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 review of the refrigerator log for the year 2017, random patient test results and interview with the laboratory director, it was determined that the laboratory failed document all corrective actions taken, including actions. The findings included: a. The refrigerator temperature log for 2017 have entries that were unacceptable and yet the laboratory did not have any corrective action documented to correct the problems. See (D5413, (b). b. For five (5) out of five (5) random patient test results reviewed from 7/27/2016 to 11/2/2017, the laboratory analyzed and reported patient test results that could have been affected by the out of ranges refrigerator temperatures. c. The laboratory director affirmed (1/4/2018, 12N), that the laboratory did not perform corrective action for the laboratory's refrigerator temperature readings outside the manufacturer's recommended acceptable ranges.