

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2112285	(X3) Date Survey Completed 09/27/2019
Name of Provider or Supplier Ayumetrix Llc	Street Address, City, State 17387 Sw 63rd Avenue, Lake Oswego, OR	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and discussion with the staff the laboratory failed to document corrective actions for issues within the laboratory. Findings include: 1. Temperature logs for the year 2019 particularly the months of April, May, July and August showed multiple days that the temperatures were out of acceptable ranges, but no corrective actions were taken. 2. Interview with 3 testing personnels revealed they were not aware that they have to document any corrective action taken when something is out of the acceptable range. 3. The Laboratory Director concur with these finding 09/27/2019 @ 16:00 PM.</p>
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>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's temperature logs and interview with testing personnels the laboratory failed to document if the temperatures were rechecked when the temperature falls outside the acceptable ranges. Findings include: 1. The surveyor requested temperature logs for the year 2018 and 2019. 2. The temperatures for the Lab Refrigerator 1 shows that the acceptable ranges are between 2-8 degrees centigrade, however, in April 2019 there were 9 out of 22 working days that the temperature were below the 2 degree centigrade. May 2019 there 2 out of 22 working days that the temperature were below 2 degree centigrade. July 2019 there were 3 out of 22 working days that the temperature were below 2 degree centigrade. August 2019 there were 2 days that the temperature were below 2 degree centigrade and 1 day that was blank meaning the temperature was not recorded. 3. Interview with 3 testing personnels revealed that they were not documenting if the unacceptable temperature were rechecked 09/27/2019 @ 16:00 PM 3. The laboratory director concur with these findings on 09/27/2019 @ 16:00 PM.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedures and interview with testing personnels the laboratory failed to document corrective actions when the temperature falls outside the acceptable ranges. Findings include: 1. The surveyor requested and the laboratory failed to provide corrective actions for temperature readings outside the acceptable ranges of 2-8 degree centigrade for Lab Refrigerator 1. 2. In April 2019 there were 9 out of 22 working days that the temperature were below the 2 degree centigrade. No corrective action were taken. 3. In May 2019 there 2 out of 22 working days that the temperature were below 2 degree centigrade. No corrective action were taken. 4. In July 2019 there were 3 out of 22 working days that the temperature were below 2 degree centigrade. No corrective action were taken. 5. In August 2019 there were 2 days that the temperature were below 2 degree centigrade and 1 day that was blank meaning the temperature was not recorded. No corrective action were taken. 3. Interview with 3 testing personnels revealed that they were not documenting corrective actions if the temperatures falls outside the acceptable ranges, 09/27/2019 @ 16:00 PM 3. The laboratory director concur with these findings on 09/27/2019 @ 16:00 PM.