Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0919496	02/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mosaic Diagnostics, Llc	9221 Quivira Road, Overland Park, KS	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon direct observation during a tour of the laboratory with Technical Supervisor #4, review of manufacturer's reagent labels and staff interview, the laboratory failed to ensure that reagents and supplies in use were not expired. Findings were: 1. During a tour of the lab the surveyors observed the following expired reagents and supplies 1.5 K2Con aqueous, expired 4-13-11 with one month epiration date. 1.33 N KOH expired 10-10-11 Sulf 1 expired 4-5-2011 2. The above findings were confirmed by interview with TS#4 , at 1100 am on February 18, 2020 in the laboratory.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on an absence of centrifuge records and interview with Technical Supervisor (TS) #4, the laboratory failed to define a function check protocol for the centifuges. Findings include: 1. No documentation was available for function checks of centrifuges for a 12 month period. 2. Interview with TS #4 on 02/18/2020 @1:30 pm confirmed the laboratory had no records of function checks for the centifuges and/or times on centifuges used in the laboratory for the past 12 months. Based on review of observation of 52 pipettes and interview with the TS#4, the laboratory failed to perform a function check on 6 out of 52 pipettes to verify the accuracy of the pipettes. Findings; 1. Observation of two of the Picus 5000 Sartarius 100-500 Ul pipettes, two of the Picus 5000 Satarius 0.5-10mL Pipettes, and VWR 100-1000 and VWR 20-200 pipettes located in the laboratory available for use showed no function checks for 2019. 2. Interview with the TS#4on February 18, 2020 at 1:35 PM confirmed, the laboratory failed to perform a function check to verify the accuracy of the volumes of 6 of 52 pipettes.