Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0720397	07/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Summit Health -	31 00 Broadway, First Floor, Fair Lawn, NJ	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Quality Manager (QM), the laboratory failed to follow the Quality Control (QC) New Lot Validation procedure for Hematology tests from December 2018 to the date of the survey. The finding includes: 1. The PM stated to run the new QC for 10 data points before putting into use. 2. The laboratory verified QC as below: a. Lot 90430804 was run two days for a total of five data points prior to use. b. Lot 83520804 expired 3/10 /19 new lot was run 3/11/19. c. Lot 90990804 was run two days for a total of six data points prior to use. 2. The QM confirmed 7/30/19 at 11:00 am that the laboratory did not follow the PM.
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 surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the Quality Manager (QM), the laboratory failed to put a new expiration date on Hematology Control material used on the Sysmex XS 1000i C-RL on the date of the survey. The QM confirmed on 7/30/19 at 10:20 am the laboratory failed to put a new expiration date on the control material.