Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2119907	03/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Leon Medical Centers, Llc	8881 Nw 18th Terrace Ste 102, Doral, FL	

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
D0000	A recertification survey conducted 03/15/2021, found the LEON MEDICAL CENTERS LLC clinical laboratory was not compliance with 42 CFR Part 493, Requirements for Laboratories.
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 observation, record review and interview, the laboratory failed to label quality control vials currently in use with an open date and new expiration date. Findings include: Examination of the EIGHT-CHECK3WP XTRA control levels in use for the Sysmex poch-100i analyzer on 3/16/2021 at 9:30 AM showed the quality control vials for level 1, 2 and 3 did not have an open date and new expiration date. Review of the PocH 100i Quality Control Assessment policy # 7009 of 10/04/2016, revealed on page 2 of 6, on section D) EIGHT-CHECK3WP XTRA Control Material revealed: 1.Storage and shelf life EIGHT-CHECK3WP XTRA is to be stored as packaged at 2-8 C before and after opening. After opening the vial is stable for 14 days if returned to the refrigerator promptly after use. During an interview on 3/15 /2021 at 9:45 AM, testing personnel 1 stated the open date and new expiration date were not labeled on the control vials.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 6/12/2019 to 3/15/2021 for hematology controls. Finding include: Review of the PocH 100i Quality Control Assessment policy # 7009 of 10/04 /2016, on page 4 of 6 section G) Starting a New Lot of Controls revealed: Parallel test new controls by analyzing the three levels of control, a minimum of twice a day for 5 days, prior to expiration of the previous lot. After a minimum of 10 data points are accumulated, enter the new targets using the mean of the analyzed points. Review of Quality Control records showed there was no lot to comparison of the hematology controls. During an interview on 3/15/2021 at 11:00 AM, the Testing Personnel 1 stated the laboratory did not perform lot to lot comparisons of hematology controls.