Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0994983	06/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Leon Medical Centers Llc	8888 Coral Way, Miami, 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 on 06/01/2020 found that Leon Medical Centers LLC Clinical Laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 on observation and staff interview, the laboratory failed to remove 1 bottle of Multistix 10SG strip and one box of I-STAT Tricontrols Control, Level 3 from the laboratory after the expiration date. Findings include: Observations taken while on tour on 6/01/2020 at 9:15 AM revealed that the laboratory had the following expired reagents: - 1 bottle of Multistix 10 SG reagent strips with lot number 811061 for urinalysis expired on 5/31/2020 located near the Clinitek analyzer. -1 box of I-STAT Tricontrols control Level 3, lot number 321113 expired on 5/31/2020 in the freezer. During an interview on 06/01/2020 at 9:30 am with testing personnel # A, he confirmed the existence of the expired reagents.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on calibration record review and staff interview, the laboratory failed to follow manufacturer instructions to do the calibration to I-STAT Point of Care Analyzer at least every 6 months for 1 (2018) out of 2 years reviewed (2018, 2019) and for the Sysmex pocH-100i Complete Blood Analyzer (CBC) for 1(2019) out of 2 years reviewed (2018 and 2019). Findings include: Review of the I-STAT Point of Care Analyzer and Sysmez pocH-100i CBC manual indicates that a calibration is needed every 6 months. Review of the I-STAT Point of Care Analyzer Calibration records showed one calibration done on 4/18/2018, the next calibration record had a date 1/03 /2019. Review of CBC analyzer records revealed one calibration done on 12/18/2018 and the next on 8/07/2019. During an interview on 6/01/2020 at 10:00 AM, the testing personnel # A confirmed that the laboratory failed to calibrate the analyzers of reference at least every 6 months for the years reviewed.