Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0156684	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mid-Suffolk Medical Care Pc	6277 Jericho Turnpike, Commack, NY	

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
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 surveyor review of the Beckman Access 2 analyzer calibration records and interview with the technical consultant and the testing person, calibration of the Beckman Access 2 analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1) The Beckman Access 2 system creates and stores calibration data for each calibration run on the analyzer. Depending on the type of assay, the system generates an associated calibration curve or a cutoff. The laboratory's calibration policy and the manufacturer of the Beckman Access 2 analyzer require analyzer calibration to be performed and the calibration curve to be updated when prompted by the analyzer. This criteria was disregarded by the laboratory from 4/24/19 through 5/6/19 when it was flagged/prompted repeatedly by the analyzer. 2) On May 15, 2019 at approximately 11:30 AM the technical consultant and the testing person confirmed surveyor's findings that the analyzer calibration curve was expired from 4/24/19 through 5/6/19 for the following analytes: Free T4, Prostate Serum Antigen (PSA), Thyroid Stimulating Hormone (TSH), Vitamin B12, Vitamin A, testosterone, total T3,

	and Folate. 3) Approximately 150 patient specimens were tested and reported for endocrinology analytes during the time period when analyzer was out of calibration.