Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0707201	01/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Clinic Of Central Utah	3650 N University Ave Ste 150, Provo, UT	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on Envoy instrument maintenance records review, lack of documentation and interview with staff, the laboratory failed to perform and document instrument maintenance as defined by the manufacturer for the Envoy instrument for 1 of 8 quarterly Sodium and Chloride electrode changes reviewed from January 2018 to January 2020, March 19. 2018. The laboratory performed approximately 8000 electrolyte tests per year. Findings include: 1. The Envoy manufacturer maintenance log review included a 3 month schedule for changing fSodium, Potassium, and Chloride electrodes. The log lacked documentation Sodium and Chloride electrodes were changed in the first quarter of 2018. 2. In an interview with staff on 01/23/2020 at approximately 2:45 P.M. staff confirmed they did not change sodium and Chloride electrodes the first quarter of 2018.
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 records review, lack of documentation, and interview with staff, the laboratory failed to verify calibration at least once every six months for the ABX Micros 60 hematology tests for 1 of 4 six month periods reviewed from January 2018 to January 2020, the first six months of 2018. The laboratory performed approximately 8000 Complete Blood Counts per year. Findings include: 1. Calibration records reviewed failed to include documentation the laboratory followed ABX manufacture's instructions to verify calibration once every 6 months. 2. In an interview with staff on 01/23/20220 at approximately 2:45 P.M., staff confirmed they missed performing calibration on the Complete Blood Count instrument the first six months of 2018.