Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2133426	08/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Usa Mobile Diagnostic Center	6304 Usa Health Blvd, Mobile, AL	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing (PT) records and an interview with the Technical Consultant, the surveyor determined the laboratory failed to implement procedures to ensure proficiency testing failures were effectively investigated to determine the cause. This was noted on four of four 2018-2019 Chemistry surveys with failing results. The findings include: 1. A review of the 2018 API (American Proficiency Institute) Chemistry PT records revealed the laboratory obtained failing scores of 20% for Pro-BNP (Beta Natriuretic Peptide) in the Event #2 and Event #3 surveys. [Note: The surveyor noted all Pro-BNP results showed a positive SDI (Standard Deviation Index) bias in both surveys, with no indication the laboratory had investigated this trend.] 2. A review of the laboratory's corrective action for Pro-BNP in Event #2 revealed the testing personnel repeated the four samples that failed, however only one was within acceptable range. There was no documentation of any further corrective action or investigation. 3. Corrective action for Pro-BNP in Event #3 revealed the testing personnel calibrated the test, and then repeated the four samples that had failed; all four were still outside the acceptable ranges. The laboratory then called Roche Technical Assistance, and the Service Technician replaced the measuring cell. There was no documentation of any further corrective action to determine if patient results were affected during the period when the measuring cell was failing. 4. A review of the 2019 API surveys, Event #1 Chemistry revealed Chloride with a failing score of 60%, and Troponin with a score of 20%. Corrective action revealed the testing personnel repeated the samples that failed, and

	all were within acceptable range. There was no documentation of any additional investigation of the original cause of the failures. (Note: The surveyor noted the Troponin results showed a positive SDI bias, and the Chloride results showed a negative SDI bias, with no indication the laboratory had investigated these trends.) 5. During an interview on 8/27/2019 at 3:00 PM, the surveyor asked the Technical Consultant if the laboratory had procedures to investigate the actual causes of PT failures to determine if the patient results had been affected; this could include review of recent calibrations, maintenance and quality controls for trends and shifts. The Technical Consultant confirmed the usual procedure was to repeat any samples with results less than 100%; the laboratory had not informed clients to review patient tests performed during the periods when PT failures had occurred to determine if patient care was impacted. SURVEYOR ID #32558 Licensure and Certification Surveyor