Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0706289	07/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kilby Correctional Facility	12201 Wares Ferry Road, Mount Meigs, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the 2016 - 2018 CAP (College of American Pathologists) Proficiency Testing records and an interview with the Technical Supervisor (also the Testing Personnel), the laboratory failed to ensure attestation statements for seven out of twelve surveys were signed by the Laboratory Director and testing personnel. The findings include: 1. A review of the CAP Syphilis Serology and Viral Marker Proficiency Testing (PT) records revealed no signatures of the Laboratory Director (LD) and/or the Testing Personnel (TP) on attestation statements for the following surveys: A) 2016-3rd Event RPR Survey: No LD B) 2017-1st Event Viral Markers: No LD C) 2017-2nd Event Viral Markers: No TP D) 2017-1st Event RPR Survey: No LD or TP E) 2017-3rd Event RPR Survey: No LD F) 2018-1st Event Viral Markers: No LD G) 2018-2nd Event Viral Markers: No LD 2. In an interview on 7/3/2018 at 11: 30 AM, the Technical Supervisor reviewed the PT records with the surveyor, and confirmed the above noted findings. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a lack humidity records, a review of the Vitros Operator's Guide and an interview with the Technical Supervisor (also the Testing Personnel), the surveyor determined the laboratory failed to monitor humidity in the room where testing was performed. The findings include: 1. During the initial laboratory tour, the Technical Supervisor listed Anti-HIV 1/2 performed on the Vitros EciQ on the laboratory test menu. 2. A review of the Vitros Operator's Guide on page 1-11 included these instructions, "...Environment Specifications ... Site Relative Humidity [RH]: 15-75 % RH non-condensing...". 3. A review of the environmental monitoring records revealed the laboratory only recorded the daily room temperatures for the testing area. There was no documentation of the daily room humidity. 4. During an interview and review of the above records on 7/3/2018 at 1:00 PM, the Technical Supervisor confirmed the laboratory has not been monitoring and recording the daily room humidity. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor