Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029494	10/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mississippi State Penitentiary	Ms Hwy 49 West, Parchman, MS	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records since the last survey on 1-24-17 and confirmation by the technical consultant, the laboratory failed to maintain a copy of attestation statements, signed by the analyst and laboratory director, proficiency testing report forms used by laboratory to record proficiency testing results, and graded results from the proficiency testing provider for a minimum of two years. Findings include: Review of proficiency testing (PT) records since the last survey on 1-24-17 and confirmation by the technical consultant revealed the laboratory failed to maintain, for a minimum of two years, a copy of the following proficiency testing records: 1. The attestation statements, signed by the analyst and laboratory director, for Immunohematology, Hematology/Coagulation, and Routine Chemistry for Events 1, 2, and 3 of 2017 and Events 1 and 2 of 2018. 2. The proficiency testing report forms used by the laboratory to record proficiency testing results for Hematology /Coagulation, and Routine Chemistry for Event 3 of 2017, Event 1 of 2018, and Event

	2 of 2018. 3. The proficiency testing provider graded results for Immunohematology for Event 2 of 2017, Immunohematology and Hematology/Coagulation for Event 1 of 2018, and Immunohematology for Event 2 of 2018.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of documentation available for review and interview with staff, the laboratory had not followed written policies to assess employees and, if applicable, technical consultant competency at least annually since their last inspection, 1/24/17. On the day of survey, there was no documentation of an annual competency or evaluation for the technical consultant of the laboratory for the years 2017 or 2018 performed by the laboratory director.
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: A Based on review of the ACL 100 Coagulation analyzer maintenance records from 1 /24/17 to the day of survey, 10/23/18, the laboratory failed to document as performed the monthly maintenance required by the manufacturer. The following maintenance was not performed: Monthly Maintenance: Clean the air filter--not performed for 2/17 through 4/17 and 6/17 through 10/18. B Based on review of the ACL 100 Coagulation analyzer maintenance records from 1/24/17 through 10/23/18, the laboratory failed to document, as performed, the annual maintenance required by the manufacturer. No annual maintenance had been performed since the last survey on 1/24/17. This included: 1. Replace the filter 2. Replace the sample reagent tube 3. Replace the waste drain tube 4. Replace the needle block 5. Replace the waste reservoir
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 a review of calibration records for the ABX Micros 60 hematology analyzer since the last survey on 1/24/17, the laboratory failed to document calibration on the analyzer every 6 months as required. Findings include: Review of calibration records for the ABX Micros 60 hematology analyzer since the last survey on 1/24/17 revealed calibration was performed on 7/26/17 then again on 7/18/18. This time period exceeds the manufacturer's calibration requirement of every 6 months.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the ACL 100 Coagulation analyzer from 2/28/17 through 10/19/18 and review of the patients in house log, it was determined 1 of the 2 levels of QC material performed were outside of the manufacturer's acceptable range on the following days when patients were tested and results reported. 11/29/17, 1/17/18, 3/12/18, 4/2/18, 4/30/18, 5/19/18, 9/17/18, 9/14 /18, 9/11/18, 9/10/18, 10/1/18, 10/8/18 Forty patients were tested on these days without QC being acceptable.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records since the last survey on 1-24-17, the laboratory director failed to ensure that all proficiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's performance for the following: 1. Immunohematology - Event 2 of 2017 and Events 1 and 2 of 2018 2. Hematology/Coagulation - Event 1 of 2018
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

	This STANDARD is not met as evidenced by: Based on review of laboratory records (including quality control, calibrations, temperature logs, maintenance and proficiency results) since the last survey on 1/24 /17 through the day of survey 7/25/18, and confirmation with staff at 3:30 pm, the technical consultant listed on the CMS (Centers of Medicare and Medicaid) 209 form before the day of survey, failed to document the review of these laboratory records. The following records were not reviewed by the technical consultant appointed during that time: 1. Laboratory task maintenance report-12/14/17 through 9/21/18 2. OPTI CCA Blood Gas analyzer maintenance (weekly, quarterly, annually, as needed) - 2/7 /17 through 10/23/18 3. All Proficiency testing results for 1st and 2nd events 2017, 1st and 2nd events of 2018