Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029494	02/21/2023
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
D0000	The following condition level deficiency was cited: D6033 42 C.F.R. 493.1409 Condition: Technical Consultant - Moderate Complexity
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records since 6/22/2021 and interview with testing personnel (TP) # 2 on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 2/21/2023, the laboratory failed to retain all proficiency testing (PT) records for at least 2 years. Findings include: 1. Review of PT records for 2021-3rd event revealed the laboratory did not retain the following records: a. Signed attestation statements b. Patient/PT lab result logs c. Submitted result sheets d. PT provider scores with documentation of review 2. Interview with TP # 2 at 11:30 a.m. on 2/21/2023 confirmed the 2021-3rd event proficiency testing documents were not retained. THIS IS A REPEAT DEFICIENCY.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records since 6/22/2021 and interview with testing personnel (TP) #2 on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to verify the accuracy of Troponin I performed

	on the LifeSign MI Troponin I test system at least twice annually in 2022. Findings Include: 1. Review of laboratory records revealed the laboratory used a proficiency testing module to verify accuracy of Troponin I performed on the LifeSign MI Troponin I test system twice annually in 2021. 2. Review of proficiency testing records for Troponin I revealed the laboratory had not enrolled in PT for Troponin I in 2022, nor had the laboratory performed any other verification of accuracy for this analyte in 2022. 3. TP #2 in an interview at 12:15 p.m. on 2/21/2023 confirmed the laboratory did not verify accuracy twice a year for Troponin I in 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual for the Mississippi State Penitentiary Laboratory, the LifeSign MI Troponin I manufacturer instructions and interviews on 2/21/2023 at 12:00 p.m. with the Health Site Administrator (HSA), Director of Nursing (DON) and Testing Personnel (TP) #2 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory procedure manual was not approved and signed by the new laboratory director who became responsible for the laboratory on 5/9/2022. Findings include: 1. The HSA, DON and TP#2 confirmed in an interview on 2/21/2023 at 12: 00 p.m. that the laboratory manual and Troponin I procedure manufacturer instructions were used as the procedures for performing Troponin I testing. 2. There was a laboratory director change on 5/9/2022. 3. On surveyor review of these manuals there was no documentation to indicate they had been approved by the new laboratory director.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the personnel testing records on 2/21/2023 and the lack of education documentation, the laboratory director did not ensure the testing personnel listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form had the appropriate education to perform moderate complexity testing prior to testing patients. Findings include: There was no documentation on 2/21/2023 available for review to indicate the laboratory personnel listed on the CMS 209 form had the education required to perform moderate complexity testing in the laboratory.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

	CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the number of deficiencies cited for technical consultant responsibilities, the technical consultant failed to provide technical oversight in accordance with paragraph 493.1413 of this subpart. Refer to D6036 - Failure to have a technical consultant who provides oversight of laboratory Refer to D6049 - Failure to document review of quality control records, temperature records and proficiency test results. Refer to D6053 - Failure to document competency evaluations for testing personnel performing moderate complexity testing at least semiannually during the first year of employment. Refer to D6054 - Failure to document annual competency evaluations for testing personnel performing moderate complexity testing. 38948
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory records on 2/21/2023 and an interview with the Health Site Administrator (HSA), Director of Nurses (DON) and Testing Personnel (TP) #2, the technical consultant listed on the CMS 209 form does not provide technical oversight of the laboratory. Findings include: 1. Review of the following deficiencies indicated the technical consultant did not provide technical oversight of the laboratory and its functions since assuming technical consultant responsibilities on 5/9/2022: a. Refer to D6049 - Failure to review quality control, temperature and proficiency testing records. b. Refer to D6053 - Failure to perform semi-annual competency evaluations on moderate complexity testing personnel c. Refer to D6054 - Failure to perform annual competency evaluations on moderate complexity testing personnel. 2. The HSA, DON and TP #2 confirmed in an interview that the technical consultant did not fulfill the responsibilities necessary to supervise the technical performance of the laboratory and staff.
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 testing records (LifeSign MI Troponin quality control logs, patient result logs, temperature records, and proficiency test records) from 9/18 /2021 through 2/20/2023 and interviews with testing personnel (TP) #2 as listed on the Centers of Medicare & Medicaid Services 209 form, HSA (Health Site

	Administrator) and the DON (Director of Nursing), at 1:00 p.m. on 2/21/2023, the technical consultant failed to document review of all records. Findings Include: 1. The surveyor reviewed laboratory records from 9/18/2021 through 2/21/2023. There was no documented review of the following records by the technical consultant: a. Life Sign MI Troponin I patient result logs which included quality control results for 9/18 /2021-2/20/2023 c. Laboratory temperature records (room, refrigerator, freezer) from 6 /23/2022 through 12/31/2022 d. Proficiency result records for 2nd event of 2021 2. The HSA, DON and TP #2 in an interview at 1:00 p.m. on 2/21/2023 confirmed there was no documented review of these records by the technical consultant.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel records (Centers for Medicare and Medicaid Services 209 personnel form) since 6/22/2021 and interview with the Health Site Administrator (HSA), Director of Nurses (DON) and Testing Personnel (TP) #2 at 3:00 p.m. on 2/21/2023, the technical consultant (TC) failed to evaluate and document the competency of TP #2, #3, #4, #5, #7 and #9 at least semiannually during the first year of employment. Findings include: 1. Review of the laboratory personnel records indicated there were no 6 month competency evaluations available for TP #2, #3, #4, #5, #7 and #9. TP #2 training date 8/4/21 - 6 month evaluation due February 2022 TP #3 hire date 3/21/2022 - 6 month evaluation due September 2022 TP #4 hire date 6/27/22 - 6 month evaluation due December 2022 TP #5 hire date 4/4 /2022 - 6 month evaluation due October 2022 TP #7 hire date 6/2022 - 6 month evaluation due December 2022 TP #9 hire date 2/1/2022 - 6 month evaluation due August 2022 2. Interview with the HSA, DON and TP #2 confirmed at 3:00 p.m. that no 6 month competency evaluation was performed on TP #2, #3, #4, #5, #7 or #9 during the first year of hire while performing moderate complexity testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with the Health Site Administrator (HSA), Director of Nursing (DON) and Testing Personnel (TP) #2, the technical consultant (TC) failed to evaluate annually and document the competency of testing personnel TP #2 and TP #9 who are responsible for performing moderate testing. Findings include: 1. The surveyor reviewed laboratory personnel records. There was no documentation of annual competency evaluations available for review: a. The TC failed to evaluate TP #2 (initial training date 8/4/2021) annually for competency in performing moderate complexity testing since 6/22/2021. b. The TC

	failed to evaluate TP #9 (hire date 2/1/2022) at least annually for competency in performing moderate complexity testing. 2. Interview with the HSA, DON and TP #2 confirmed no annual competency evaluations for TP #2 and TP #9 had been documented as performed by the technical consultant for the year 2022 and 2023.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records available on 2/21/2023, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with the Health Site Administrator (HSA), Director of Nursing (DON) and TP#2 at 3:00 p. m. on 2/21/2023, the laboratory director did not ensure all testing personnel as listed on the CMS 209 personnel form had received the appropriate documented training prior to performing Troponin I testing on the Life Sign MI Troponin I test cassette kit. Findings Include: 1. Based on review of laboratory personnel records and lack of training documentation on 2/21/2023, TP#3 through TP #9 had no documented initial training for moderate complexity Troponin I testing prior to performing testing on patients. TP #3 - hire date - 3/21/2022 TP #4 - hire date - 6/27/2022 TP #5 - hire date - 4/4/2022 TP #6 - hire date - 10/3/2022 TP #7 - hire date - 6/2022 TP #8 - hire date - 10 /3/2022 TP #9 - hire date - 2/1/2022 2. The HSA, DON and TP #2 confirmed in an interview at 3:00 p.m. on 2/21/2023 that no initial training for Troponin I testing had been documented for TP #3 through TP #9 prior to testing patients.