Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1096223	05/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mississippi Public Health Laboratory	570 East Woodrow Wilson, Jackson, 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
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 and interview with the laboratory director, the laboratory failed to verify the accuracy HIV NAAT, EEE IgM, Zika Virus IgM, Chikungunya IgM, and Dengue IgM testing twice per year in 2021 and 2022. Finding included: 1. Review of in-house proficiency testing records for HIV NAAT revealed only one annual test verification was performed in 2021 and none in 2022. The laboratory performs approximately 40 tests each year. 2. Record review of in-house proficiency testing records for EEE IgM, Zike Virus IgM, chikungunya IgM, Dengue IgM revealed the laboratory did not perform verification twice annually in 2021 and 2022. The laboratory performed 4 tests between 2021 and 2023 to date of survey. 3. The laboratory director confirmed the above findings on May 18, 2023 at 1:30PM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on direct observation and interview with staff, the laboratory failed to implement a written procedure for preparing their subculture quality control (QC) plates (5 of 5 plates observed). Findings included: 1. During a tour of the special microbiology laboratory on 5/18/23 at 10:10 am, the following subculture QC plates were observed stored in the refrigerator: "5/1 Escherichia coli ATCC 25922 beads" "5 /1 Klebsiella pneumoniae ATCC 1705" "5/1 Klebsiella pneumoniae ATCC 1706" "5 /1 Pseudomonas aeruginosa ATCC 27853 beads" "5/17 EC; PA; 1705; 1706" (EC = Escherichia coli; PA = Pseudomonas aeruginosa; 1705 and 1706 = Klebsiella pneumoniae) During an interview on 5/18/23 at 10:15 am with Testing Person -6 (TP-6) and the special microbiology technical supervisor, they stated the above subculture QC plates were used for gram stain QC and for enteric testing. On 5/18/23 at 10:15 am, the following was observed on the special microbiology's dry eraser board, "8/17 /20 - Sub QC from beads monthly (P. aer/Enteroc subbed twice monthly)." A written procedure was requested for preparing and storing the subculture QC plates. 2. On 5 /18/23 at 11: 50 am, the special microbiology technical supervisor confirmed a written procedure approved by the laboratory director had not been implemented. Word Key: ATCC = American Type Culture Collection Sub = Subculture P. aer = Pseudomonas aeruginosa Enteroc = Enterococcus faecalis
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 direct observation, interview with the Molecular Biology Technical Supervisor, and lack of documentation, the laboratory failed to monitor room temperature and define criteria for proper storage of molecular biology reagents in room 4301 as evidenced by: 1.In direct observation on May 17, 2023 @1314 the following reagents were stored in Room 4301 without temperature monitoring according to the manufacturer's instructions: a.11 boxes of Magna Pure 96 Cartridge lot #22121431, expiration date 1-31-2025. The manufacturer required storage temperature is 2 to 25 degrees C. b.3 boxes of Magna Pure 96 system fluid. The manufacturer required storage temperature is 15 to 25 degrees C. 2.The laboratory did not provide documentation that they monitored room temperature for proper storage

	of reagents. 3.In interview with the Molecular Biology Technical Supervisor on May 17, 2023 @ 1320 she stated that they had just moved some of the reagents over for temporary storage, and they had forgotten to monitor.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, observation, interview with the technical supervisor, and review of a patient test report, the laboratory used gram iodine past its expiration according to manufacturer's instructions (three-month stability, once reconstituted) for one of one patient in 2023 (random sampling). Findings included: 1. Review of Remel Gram Iodine manufacturer's instructions stated, "10. PROCEDURE ...Use Gram Iodine within 3 months after reconstitution." 2. During a tour of the special microbiology laboratory on 5/18/23 at 2:43 pm, the following was observed stored next to the sink: One bottle of Gram Iodine with written documentation of "op 2/14/23" (op = opened) (Lot #125049, expiration date 5 /12/24). The elapsed days from the date of reconstitution to the manufacturer's stability (three months) was 93 days. 3. During an interview on 5/18/23 at 2:43 pm, the special microbiology technical supervisor was asked for the stability of the Gram Iodine once reconstituted, he stated until the expiration on the bottle. 4. Review of patient test reports revealed a gram stain result (gram negative cocci) on 5/17/23 at 8: 27 am for patient 135SM0001. The laboratory used expired Gram Iodine on one of one patient reviewed.
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 maintenance record review and interview with the technical supervisor the laboratory failed to perform and document the microscope maintenance specified by the manufacturer for the mycobacteriology section in 2021, 2022 and 2023. Findings included: 1. Review of the Mycobacteriology records found no records for the microscopes used on a daily basis. The laboratory has 3 microscopes(SN# 943787, 78384 and 3551692) in which the laboratory did not document any maintenance activities. The laboratory Maintenance procedure states, "All instrument maintenance and calibration procedures will be perfromed with a frequency at least as stringent as manufacturerer recommendation". 2.The manufacturer instructions for the Olympus and Nikon microscopes is to perform cleaning each day of use. The laboratory did not have any records for review in 2021, 2022, or 2023 to day of survey. The laboratory performs approximately 11000 Mycobacteriolgy tests per year. 3. The technical supervisor confirmed on 5/18/2023 at 11:00am that the laboratory did not have documentation for microscope daily maintenance.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature charts for 2022 including room temperature in lab room 4411 (TB Lab), Incubator #7 in room 4409, Refrigerator #1 in room 4411, HIV refrigerator in room 3406, and RPR refrigerator in room 3406, and interview with the Technical Supervisor at 1:30 p.m. on 5/28/2023, the laboratory failed to document corrective actions when the temperatures recorded exceeded the specified ranges on a total of 56 of 795 days reviewed. Findings include: 1) The temperature charts in use for all refrigerators, freezers, and room temperature recordings specify, "Circle any unacceptable readings in RED and record corrective action below." There is a box at the end of each month for documented review. 2) Reviews of all temperature charts were performed monthly by the technical supervisor. a. The room temperature chart for the TB Lab - Room 4411 specified the temperature should be between 18 and 30 degrees Celsius. Nineteen days out of 218 in 2022 were out of range with no corrective action documented. b. The temperature chart for Incubator #7 in room 4409 specified the temperature should be between 55 and 65 degrees Celsius. Four days out of 225 in 2022 were out of range with no corrective action documented. c. The temperature chart for Refrigerator #1 in room 4411 specified the temperature should be between 2 and 8 degrees Celsius. Twelve days out of 225 in 2022 were out of range with no corrective action documented. d. The temperature chart for the HIV Refrigerator in room 3406 specified the temperature should be between 2 and 8 degrees Celsius. Eleven days out of 64 reviewed (July-September 2022) were out of range with no corrective action documented. e. The temperature chart for the RPR Refrigerator in room 3406 specified the temperature should be between 2 and 8 degrees Celsius. Ten days out of 63 reviewed (July-September 2022) were out of range with no corrective action documented. 3) The technical supervisor confirmed in an interview at 1:30 p.m. on 5/18/2023 that no corrective action had been documented for the out-of-range temperatures.