Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1096223	12/18/2025
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
D0000	Federal surveyors from the Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an announced CLIA recertification survey at the Mississippi Public Healthy Laboratory from December 16, 2025 to December 18, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be out of compliance with condition-level CLIA requirements, the following condition level and standard level deficiencies were found. 493.1250 - Analytical Sytems 493.1441 - Laboratory Director
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 review of proficiency testing (PT) records and interview with the section team leads, the laboratory failed to sign PT attestation forms for two out of three events in 2024 and two out of six events in 2025. Findings: 1. Review of the College of American Pathologist (CAP) hematology PT records on December 18, 2025 revealed the following attestation were not signed by the laboratory Director/ designees: a. CAP - FH13 - B - 2024. b. CAP - FH13 - C - 2024. 2. Review of the College of American Pathologist (CAP) Special Microbiology PT records on December 18, 2025 revealed the following attestation were not signed by the laboratory Director/ designees: a. CAP - GIP5 - A - 2025. b. CAP - IDR - A - 2025. 3. Interviews with the laboratory section teams leads on December 18, 2025 at 4:00 pm confirmed PT records were not signed by the LD or designee. Key: FH13 - HEMATOLOGY AUTOMATED DIFFERENTIAL SERIES. IDR - INFECTIOUS DISEASE, RESPIRATORY PANEL. GIP5 - GASTROINTESTINAL PANEL, 5 CHALLENGE.

D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on the review of the laboratory's client service manual, review of TB EIA request forms, and interview with the chemistry section lead, the laboratory failed to ensure the incubation temperature for patient specimens was documented on a sample of four of four request forms submitted for TB EIA testing in 2025. Findings: 1. The Mississippi Public Health Laboratory (MPHL) Guide to Services under TB EIA (QuantiFeronTB Gold Plus) - Incubation and Storage Requirements: stated, "After filling, the contents of the tubes MUST be thoroughly mixed by firmly shaking. The tubes must be transferred to a 37C 1C incubator as soon as possible and within 16 hours of collection. Prior to incubation, maintain tubes at room temperature (22C 5C); Do not refrigerate or freeze the blood samples. Incubate the tubes UPRIGHT at 37C for 16 to 24 hours. After incubation, tubes must be received within 72 hours and may be held between 4C and 27C. Do not centrifuge tubes prior to shipping." 2. A Review of four TB EIA test request forms on December 17, 2025 revealed incubation was not documented or provided by individuals submitting specimen to the laboratory: a. MRN: 4632253 b. MRN: 2173664 c. MRN: 4632320 d. MRN: 3355791 3. Annually the laboratory receives 1,864 TB EIA specimens for testing. 4. The Chemistry section lead confirmed the request forms did not include the incubation temperature on December 17, 2025 at 11:35 am. Key: MRN - Medical Record Number TB EIA - Tuberculosis enzyme immunoassay C - Celcuis.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manuals, manufacturer's instructions, laboratory records, patient records, and laboratory staff interviews, the laboratory

	failed to meet the analytic system requirements. Findings: 1. The laboratory failed to follow their own procedure for monthly quality control testing. Refer to D5401, I. 2. The laboratory failed to follow their own procedure for documentation of MGIT sterility verification. Refer to D5401, II. 3. The laboratory failed to establish quality control procedures and procedure for entering results in the patient records for manual differential cell review. Refer to D5403. 4. The laboratory failed to follow manufacturer's instructions for acid fast bacterium (AFB) staining by Ziehl-Neelsen examination. Refer to D5411, I. 5. The laboratory failed to follow manufacturer's instructions for gram staining. Refer to D5411, II. 6. The laboratory failed to follow manufacturer's instructions for the aliquotting vials of reconstituted Bacterial Test Standard (BTS) used by the MALDI Biotyper. Refer to D5411, III. 7. The laboratory failed to define and/or monitor an acceptable room temperature and/or humidity range consistent manufacturer's requirements. Refer to D5413, I, II, III, IV, V, VI, VII, VIII, IX. 8. The laboratory failed to label secondary containers with reagent identification information, storage requirements and expiration dates. Refer to D5415, I and II. 9. The laboratory failed to ensure that expired reagents were not available for use. Refer to D5417, I, II, and III. 10. The laboratory failed to perform monthly maintenance per manufacturer's instructions for the Cepheid GeneXpert Infinity molecular diagnostic system. Refer to D5429. 11. The laboratory failed to perform quality control (QC) at least once each day of patient testing for Biofire Micro arrays in use. Refer to D5445. 12. The laboratory failed to test and document hematological staining materials for their staining characteristics. Refer to D5473. 13. The laboratory failed to check each batch of media for the ability to support growth for microbiology growth media. Refer to D5477 I and II. 14. The laboratory failed to perform comparison on the Biofire Filmarray used to perform the Gastrointestinal (GI) Panel. Refer to D5775.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on observation, review of laboratory procedure, Cepheid GeneXpert quality control (QC) records, patient records, and confirmed in staff interview, the laboratory failed to follow their own procedure for monthly quality control testing for one of four months in 2025. Findings: 1. During a tour of the mycobacteriology testing area (Room 4112) on 12/16/2025 at 2:10 pm, a Cepheid GeneXpert Infinity instrument (Serial Number 843224) was observed to be in use by the laboratory. 2. The laboratory procedure titled "GeneXpert MTB/RIF" stated " ...Quality Control Requirements ...External Controls At the beginning of each month, one negative control prepared from an ATCC non-tuberculous mycobacterial strain, one positive control prepared from a previously identified and confirmed Rifampin resistant MTB isolate and one control prepared from a previously identified Rifampin susceptible MTB isolate will be tested. Operators are required to perform external QC before reporting patient results ..." 3. Review of Cepheid GeneXpert quality control (QC) records from July 2025 through October 2025 revealed the laboratory failed to perform monthly QC for August 2025. 4. Review of the laboratory's patient records revealed the following patients were tested on the Cepheid GeneXpert in August 2025: Date tested 08/01/2025; Patient 25M-213TB0007 Date tested 08/04/2025;

	Patient 25M-213TB0009 Date tested 08/04/2025; Patient 25M-214TB0001 Date tested 08/05/2025; Patient 25M-216TB0007 Date tested 08/05/2025; Patient 25M-216TB0008 Date tested 08/04/2025; Patient 25M-216TB0009 Date tested 08/05/2025; Patient 25M-216TB0013 Date tested 08/05/2025; Patient 25M-217TB0016 Date tested 08/06/2025; Patient 25M-217TB0017 Date tested 08/07/2025; Patient 25M-218TB0010 Date tested 08/11/2025; Patient 25M-220TB0008 Date tested 08/13/2025; Patient 25M-224TB0019 Date tested 08/15/2025; Patient 25M-226TB0010 Date tested 08/15/2025; Patient 25M-226TB0011 Date tested 08/15/2025; Patient 25M-226TB0015 Date tested 08/19/2025; Patient 25M-230TB0003 Date tested 08/19/2025; Patient 25M-230TB0004 Date tested 08/26/2025; Patient 25M-233TB0008 Date tested 08/26/2025; Patient 25M-237TB0006 Date tested 08/26/2025; Patient 25M-237TB0009 Date tested 08/26/2025; Patient 25M-237TB0010 Date tested 08/27/2025; Patient 25M-238TB0020 Date tested 08/29/2025; Patient 25M-240TB0011 Date tested 08/29/2025; Patient 25M-240TB0013 Date tested 08/29/2025; Patient 25M-241TB0012 5. In an interview on 12/17/2025 at 7:50 am, the Mycobacteriology Technical Supervisor confirmed the findings. Word Key: ATCC=American Type Culture Collection II. Based on observation, review of laboratory procedure, BACTEC MGIT 960 records, and confirmed in staff interview, the laboratory failed to follow their own procedure for documentation of MGIT sterility verification for 59 of 59 days of specimen processing. 1. During a tour of the mycobacteriology testing area (Room 4411) on 12/16/2025 at 1:55 pm, a BACTEC MGIT 960 instrument (Serial Number MG7570) was observed to be in use by the laboratory. Two other MGIT 960 instrument were also observed but not in use by the laboratory. These were designed as MGIT 1 (Serial Number 3641 and MGIT 2 (Serial NumberMG3880). 2. In an interview on 12/16/2025 at 2:13pm, the Mycobacteriology Technical Supervisor stated that the laboratory stopped using MGIT 1 and MGIT 2 in August 2025. 3. The laboratory procedure titled "Growth and Detection-Liquid MGIT Media" stated " ... 3.0 Two sterility controls or blanks will be inoculated daily. 3.1 One MGIT tube without an accession number will be placed in the tube rack and one MGIT tube will be placed behind the last patient specimen. 3.2 These tubes will act as sterility QC tubes ..." 4. Review of the laboratory record titled "MGIT Processing Sterility Verification Log" from 08/04//2025 through 11/04/2025 revealed the laboratory documented sterility for MGIT bottles loaded onto MGIT 1 and MGIT 2 for each of the 59 days of patient testing. The laboratory failed to document sterility verification for the MGIT 960 in use (Serial Number MG7570). 5. In an interview on 12/16/2025 at 2:13pm, the Mycobacteriology Technical Supervisor confirmed the laboratory failed to document sterility verification for the MGIT currently in use.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering

	substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of hematology testing procedures, and interview with chemistry lead, the laboratory failed to include quality control (QC) procedures in the manual differential cell review procedure for two of two years (December 2023 to December 2025). Findings: 1. Review of the manual differential cell review procedure on December 17, 2025, revealed the procedure did not include QC procedures for checking staining materials for their ability to stain cells. 2. On December 17, 2025, at 1:00 pm the chemistry lead confirmed the laboratory never performed QC for manual differential cell reviews from December 2023 to December 2025.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory procedure, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for acid fast bacterium (AFB) staining by Ziehl-Neelsen examination for 20 of 20 months. Findings: 1. The manufacturer's instructions for Remel TB Ziehl-Neelsen stains (40102 Revised April 10, 2013) stated " ...Procedure ...4. Decolorize with TB Decolorizer for 3 minutes. Rinse with water and drain ..." 2. The laboratory procedure titled "AFB Staining by Ziehl-Neelsen Examination" (Activation Date: 04 /18/2024) stated " ...C. Ziehl-Neelsen Staining ...f. Flood slides with Decolorizer g. Wait 2" (minutes) ..." The laboratory procedure did not follow the manufacturer's stated time of three minutes. 3. In an interview on 12/17/2025 at 7:50am, the Mycobacteriology Technical Supervisor confirmed the laboratory procedure did not follow manufacturer's instructions. II. Based on observation, review of manufacturer's instructions, laboratory procedure, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for gram staining for 24 of 24 months. Findings: 1. During a tour of the special microbiology area on 12/18/2025 at 11:30 am, one bottle each of Remel Gram Crystal Violet, Gram Decolorizer, Gram Iodine, and Gram Safranin were observed open and in use by the laboratory. 2. The manufacturer's instructions for Remel gram stain reagents stated " ...Procedure ...2. Place a slide on the staining rack and overlay with Gram Crystal Violet for 1 minute 3. Wash thoroughly with water and overlay with Gram iodine mordant for 1 minute 4. Flood with Gram Decolorizer until the solvent flows colorless from the slide (10-30 seconds) ..." 3. The laboratory procedure titled "Gram Stain" (Activation Date: 11/13 /2023) stated " ...Procedural Steps ...2. Flood slide with crystal violet and allow it to remain on the surface without drying for one minute. Rinse with tap water shaking off excess. 3. Flood slide with iodine and allow it to remain on the surface without drying

	for one minute. Rinse with tap water shaking off excess. 4. Flood the slide with decolorizer for 10 seconds and rinse it off immediately with tap water ..." The laboratory procedure differed from the manufacturer's instructions. The laboratory procedure included a "slide rinse" between steps 3 and 4. 4. In an interview on 12/18 /2025 at 11:55 am, the Special Microbiology Technical Supervisor confirmed the laboratory procedure did not follow manufacturer's instructions. III. Based on observation, review of manufacturer's instructions, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for the aliquotting of two of two vials of reconstituted Bacterial Test Standard (BTS) used by the MALDI Biotyper. Findings: 1. During a tour of the Special Microbiology area (Room 4101), two Bruker MALDI Biotyper instruments (Serial Numbers 8269944.03692 and 189013270475) for organism identification were observed and in use. 2. Also observed in the storage area in a Revco Freezer were two vials of reconstituted BTS reagent (Lot number 6030425002, expiration date 01/05/2026). One of the vials had "TB" written on the cap. The reconstituted vials were not aliquoted. 3. The manufacturer's instructions for the Bruker MALDI Biotyper stated " ...3.6.2 Storage of Reconstituted US IVD BTS Solution If reconstituted US IVD BTS solution is not to be used immediately, store as described here: 1. Transfer aliquots of a volume appropriate to your daily workflow into screw-cap micro tubes (0.5mL) and close tubes tightly ..." 4. In an interview on 12/18/2025 at 12:21pm, the Special Microbiology Technical Supervisor stated the laboratory reconstituted the BTS and did not aliquot the reagent. This confirmed the findings. 5. The laboratory has an annual volume of 1,678 organism identifications performed on the Bruker MALDI Biotyper.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on observations of the laboratory, review of manufacturers' instructions, laboratory procedure, environmental records, and an interview with laboratory staff, the laboratory failed to ensure manufacturer's specifications for room temperature and /or humidity were followed for two of two years. Findings: 1. The MS Public Health Laboratory Clinical Services Quality Management Systems Procedure, 7.5 Inventory control states, "The laboratory has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates. A regular inventory is performed". 2. During a tour of the central supply room (room 1101) on December 17, 2025, at 6:10 am, Aptima Collection kits and QuantiFERON blood collection tubes were observed to be stored on shelves in the supply room. 3. Review of the manufacturer's temperature requirement on the boxes revealed the following temperature requirements: a. Aptima Urine Specimen Collection Kit: 15 - 30 Degrees Celsius. b. Aptima Multitest Swab Specimen Collection Kit: 15 - 30 Degrees Celsius. c. QuantiFERON - TB Gold Plus Blood

Collection Tubes: 4 - 25 Degrees Celsius. 4. The Laboratory was unable to provide temperature monitoring records for the central supply area. 5. The administrative Service director confirmed the finding above on December 17, 2025, at 7:00 am. II. Based on observations of the laboratory, review of manufacturers' instructions, laboratory procedure, environmental records, and interview with laboratory staff, the laboratory failed to ensure manufacturer's specifications for room temperature and/or humidity were followed for two of two years. Findings: 1. The MS Public Health Laboratory Clinical Services Quality Management Systems Procedure, 7.5 Inventory control states, "The laboratory has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates. A regular inventory is performed". 2. During a tour of the Special Microbiology (room 4101) on December 17, 2025, at 10:25 am, two Biofire FilmArray were observed to be in use in the laboratory. 3. Review of the Biofire FilmArray 2.0 testing area revealed one box of FilmArray Gastrointestional (GI) Panels with the storage temperature of 15 - 25 degrees Celsius. 4. Review of the laboratory's environmental records from January 2025 through November 2025 for Room 4101 revealed the laboratory established an acceptable temperature range of 18 - 27 degrees Celsius, which exceeded the manufacturer's upper limit by two degrees Celsius. 5. In an interview on December 17, 2025, at 10:30 am, the Special Microbiology Technical Supervisor confirmed the above findings. III. Based on observations of the laboratory, review of manufacturers' instructions, laboratory procedure, environmental records, and interview with laboratory staff, the laboratory failed to ensure manufacturer's specifications for room temperature and/or humidity were followed for two of two years. Findings: 1. The MS Public Health Laboratory Clinical Services Quality Management Systems Procedure, 7.5 Inventory control states, "The laboratory has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates. A regular inventory is performed". 2. During a tour of room 4101 on December 17, 2025, at 10:25 am, two Biofire FilmArray were observed to be in use in the laboratory. 3. Review of the Biofire Film Array 2.0 Operators Manual, Chapter 4: Performance Specifications BioFire 2.0, System Specifications, Operations Specification stated, "15C to 30C @ 20 to 80% humidity (non-condensing)". 4. Review of room 4101 temperature logs revealed the laboratory failed to establish humidity reference ranges. 5. In an interview on December 17, 2025, at 10:35 am, the Special Microbiology Technical Supervisor confirmed the above findings. IV. Based on observations of the laboratory, review of manufacturers' instructions, laboratory procedure, environmental records, and interview with laboratory staff, the laboratory failed to ensure manufacturer's specifications for room temperature and/or humidity were followed for two of two years. Findings: 1. The MS Public Health Laboratory Clinical Services Quality Management Systems Procedure, 7.5 Inventory control states, "The laboratory has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates. A regular inventory is performed". 2. During a tour of the Chemistry Laboratory (room 3102) on December 17, 2025, at 12:30 pm, the following reagents were observed stored at room temperature and instruments were observed in use: Reagents: a. 5 Boxes of Beckman Coulter DxH Cleaner. b. 4 boxes of Beckman CoulterDxH Diff Pack. c. 4 bottle of Beckman Coulter Wash Solution. d. 1 bottle of Wex-Code 1:128. e. 3 boxes of Beckman CoulterLatron CP-X. Instruments: a. One Beckman Coulter AU480. b. One DaiSorin Liaison XL. 3. Review of the laboratory's environmental records from January 2025 through November 2025 for Room 3102 revealed the laboratory established an acceptable room temperature range of 15 - 40 degrees Celsius, and an acceptable humidity of 10% to 85%. 4. Review of reagent bottles, and instrument manuals revealed, the manufacturer established ranges for

ambient room temperature and/or humidity: Reagents: a. Beckman Coulter DxH Cleaner: 2 - 25 degrees Celsius. b. Beckman CoulterDxH Diff Pack: 2 - 25 degrees Celsius. c. Beckman Coulter Wash Solution: 2 - 25 degrees Celsius. d. Bottle of Wex-Code 1:128: 15 - 30 degrees Celsius. e. Beckman CoulterLatron CP-X: 2 - 30 degrees Celsius. Instruments: a. The Beckman Coulter AU480 chemistry analyzer user guide, temperature and humidity conditions when in use stated, ...room between 18 and 32 degrees Celsius and the humidity between 20% RH and 80% RH with no condensation. b. One DaiSorin Liaison XL instructions for use, 10.7 Environmental conditions stated, "operating: 15 - 32 degrees Celsius." 5. Review of the clinical chemistry temperature and humidity logs revealed the laboratory exceeded the manufacturer's upper limits for room temperature and humidity for the above reagents and instruments in use. 6. In an interview on December 17, 2025, at 12:15 pm, the Clinical Chemistry Technical Supervisor confirmed the above findings. Key: RH = Relative Humidity 38798 V. Based on observation during a laboratory tour, review of relative humidity (RH) records for room number 3401, instrument operator's manual, and interview with the Immunology Technical Supervisor (ITS), the laboratory failed to define an acceptable RH consistent with the instrument manufacturer's requirements for 12 of 12 months in 2025. Findings: 1. During a tour of the Immunology/STD laboratory on 12/17/2025 at approximately 11:30 AM, one BioRad Geenius Reader was observed used for Human Immunodeficiency Virus (HIV) Supplemental Assay in room number 3401. 2. A review of the RH records for room number 3401 revealed an acceptable operating RH range from 20% to 85%. 3. A review of the BioRad Geenius reader operator's manual revealed the following: Environmental / Climate Requirements Relative Humidity (non-condensing) = 20% to 80% 4. In an interview on 12/17/2025 at approximately 11:55 AM, the ITS confirmed the laboratory failed to define an acceptable room humidity range, in room number 3401, consistent with the instrument manufacturer's requirements for 12 of 12 months in 2025. VI. Based on observation during a laboratory tour, review of room temperature (RT) records, and interview with the Immunology/Sexually Transmitted Disease (STD) Testing Personnel (TP), the laboratory failed to define and monitor an acceptable RT range consistent with the specimen testing kit manufacturer's requirements for 2171 of 2171 test specimens. Findings: 1. During a tour of the Immunology/STD laboratory the following was observed in the accessioning room adjacent to room number 3304: Stored in specimen racks on counter tops in an open room were the following: Chlamydia trachomatis/Neisseria gonorrhea (CT/GC) specimen pending testing = 1784. Trichomonas Vaginalis (TV) specimen pending testing = 387 Specimen collection dates ranged from 11/19/2025 to 12/17/2025. 2. A request for room temperature records for the accessioning room, adjacent to room number 3304, resulted in no RT records. 3. In an interview on 12/18/2025 at approximately 3:40 PM, the Immunology/STD TP confirmed the accessioning room, where the 2171 CT/GC/TV specimen pending testing were stored, was not monitored for RT and no acceptable RT range had been defined by the laboratory for that room. VII. Based on observation during a laboratory tour, review of the freezer temperature records, reagent manufacturer's instructions for use (IFU), and interview with the Virology Technical Supervisor (VTS), the laboratory failed to define an acceptable freezer temperature range consistent with reagent manufacturer's requirements for 4 of 4 boxes of reagent kits. Findings: 1. During a tour of the laboratory room number 4309 on 12/18/2025 at approximately 11:30 AM, a frost-free freezer (serial number: LA32304091) was observed being used to store the following: SuperScript III Platinum One-Step Quantitative RT-PCR System 1 box in use, Lot #2838628, Expiration date: 01/18/2026 3 boxes not in use, Lot #2945879, Expiration date: 09/11 /2026 2. A review of the frost-free freezer temperature records, from 01/01/2025 to 12 /17/2025, revealed an acceptable temperature range of -15C to -25C, which was

defined by the laboratory. 3. A review of the SuperScript III Platinum One-Step Quantitative RT-PCR System manufacturer's IFU revealed the following storage requirement: "Store components at -20C. Stability can be extended by storing at -80 C." 4. In an interview on 12/18/2025 at approximately 12:00 PM, the VTS confirmed the acceptable frost-free temperature range defined by the laboratory, which stored 4 of 4 boxes of SuperScript III Platinum One-Step Quantitative RT-PCR System, was -15C to 25C. VIII. Based on observation during a laboratory tour, review of reagent manufacturer's instructions for use (IFU), and interview with the Virology Technical Supervisor (VTS), the laboratory failed to store one of one box of reagent kit as required by the reagent manufacturer. Findings: 1. During a tour of the laboratory room number 4309 on 12/18/2025 at approximately 11:30 AM, a frost-free freezer (serial number: LA32304091) was observed being used to store the following: AgPath-ID One-Step RT-PCR Reagents 1 box in use, Lot #2506167, Expiration date: 07/02 /2026 2. A review of the AgPath-ID One-Step RT-PCR Reagent manufacturer's IFU revealed the following storage requirement: "Store the AgPath-ID One-Step RT-PCR reagents in a -10C to -30C non-frost-free freezer." 3. In an interview on 12/18/2025 at approximately 12:00 PM, the VTS confirmed one of one box of AgPath-ID One-Step RT-PCR Reagent kit was stored in a frost-free freezer (serial number: LA32304091). 46043 IX. Based on observation, review of manufacturers' instructions, laboratory procedure, environmental records, and confirmed in staff interview, the laboratory failed to ensure manufacturer's specifications for room temperature and/or relative humidity for eleven of eleven months. Findings: A. Cepheid GeneXpert Infinity molecular diagnostic system 1. During a tour of the mycobacteriology testing area (Room 4112) on 12/16/2025 at 2:10 pm, a Cepheid GeneXpert Infinity instrument (Serial Number 843224) was observed to be in use by the laboratory. 2. Review of the manufacturer's instructions stated " ...4.4 Operational Environmental Parameters ... Ambient humidity: 20% - 80%, non-condensing ..." 3. Review of the laboratory's environmental records from January 2025 through November 2025 for Room 4112 revealed the laboratory had an acceptable humidity range of 10% - 95%. This range exceeded the manufacturer's lower limit of 20% and higher limit of 80%. Further review of the environmental record showed the following documented humidity readings that were out of the manufacturer's specified range: Date: 07/17/2025; Documented humidity 82% Date: 09/18/2025; Documented humidity 81% Date: 09/24 /2025; Documented humidity 84% Date: 09/25/2025; Documented humidity 84% Date: 10/01/2025; Documented humidity 82% Date: 10/06/2025; Documented humidity 83% Date: 10/21/2025; Documented humidity 82% Date: 11/07/2025; Documented humidity 81% Date: 11/14/2025; Documented humidity 84% 4. In an interview on 12/16/2025 at 2:13pm, the Mycobacteriology Technical Supervisor confirmed the findings. B. Bruker MALDI Biotyper microorganism specimen preparation 1. The manufacturer's instructions for the Bruker MALDI Biotyper (Revision B September 2020) stated " ...2.4 Environmental Requirements-Sample Preparation Test organism samples intended to be analyzed in the MALDI Biotyper Sirius CA System must be prepared under the following conditions: 20C - 25C. For best results, preparation of all solutions, Standard Solvent, and the entire sample preparation process ...must be performed under controlled room temperature. 2. In an interview on 12/16/2025 at 2:56pm, the mycobacteriology Technical Supervisor (TS) was asked where the mycobacteriology specimens were processed for testing on the MALDI. The TS stated room 4403. 3. Review of the laboratory's environmental records from January 2025 through Novemeber 2025 for Room 4403 revealed the laboratory's acceptable temperature range for Room 4403 was 15-30C. This range exceeded the manufacturer's lower limit of 20C and higher limit of 25C 4. The laboratory had an annual volume of 705 tests for mycobacterium identification using the Bruker MALDI system. 5. In an interview on 12/16/2025 at 2:56 pm, the

	Mycobacteriology Technical Supervisor confirmed the findings. C. Ziehl-Neelsen staining reagents 1. During a tour of the mycobacteriology testing area (Room 4409) on 12/16/2025 at 1:50 pm, the following Ziehl-Neelsen staining reagents were opened and in-use: One bottle Remel TB Ziehl-Neelsen Carbolfuchsin; Lot number 147214; Expiration date 03/29/2026 One bottle 3% Acid; No lot number or expiration date documented on container One bottle Remel TB Methylene Blue; Lot number 148583; Expiration date 05/10/2026 2. The manufacturer's instructions for Remel TB Ziehl-Neelsen stains (40102 Revised April 10, 2013) stated " ...Storage Store product in its original container at room temperature (20- 25C) until used." 3. Review of the laboratory's environmental record from January 2025 through November 2025 for Room 4409 revealed an acceptable room temperature range of 18 - 30C. This range exceeded the manufacturer's lower limit of 20C and higher limit of 25C 4. In an interview on 12/16/2025 at 1:55pm, the Mycobacteriology Technical Supervisor confirmed the findings. D. Becton Dickinson BACTEC MGIT 960 instrument 1. During a tour of the mycobacteriology testing area (Room 4411) on 12/16/2025 at 1: 55 pm, a BACTEC MGIT 960 instrument (Serial Number MG7570) was observed to be in use by the laboratory. 2. The manufacturer's instrument user's manual for the BACTEC MGIT 960 instrument stated " ...Environmental Requirements ...Operating Conditions Temperature 19 - 30C ...Humidity 30-80%, non-condensing ..." 3. Review of the laboratory's environmental record for Room 4411 from January 2025 through November 2025 revealed the laboratory's acceptable room temperature range of 18 - 30C and acceptable humidity range of 20 - 90%. This range exceeded the manufacturer's room temperature lower limit of 19C and exceeded the manufacturer's lower humidity limit of 30% and high humidity limit of 80%. 4. In an interview on 12 /16/2025 at 2:31 pm, the Mycobacteriology Technical Supervisor confirmed the findings E. Cepheid GeneXpert MTB/RIF reagent cartridges 1. During a tour of the mycobacteriology testing area (Room 4404) on 12/16/2025 at 2:46 pm, the following Cepheid GeneXpert MTB/RIF reagent cartridges were observed stored in the room: One box; Lot number 1001486582; Expiration date 05/23/2027 Fifteen boxes; Lot number 101498758; Expiration date 09/12/2027 2. The manufacturer's instructions for the Cepheid GeneXpert MTB/RIF reagent cartridges (GXMTB/RIF-US-10) stated " ... 6.2 Storage and Handling Store the Xpert MTB/RIF Assay cartridges and reagents at 2 - 28C ..." 3. The laboratory procedure titled "GeneXpert MTB/RIF" stated " ...Note: Store the Xpert MTB/RIF Assay cartridges and reagents at 2 - 28C ..." 4. Review of the laboratory's environmental record for Room 4404 from January 2025 through November 2025 revealed the laboratory's acceptable room temperature range of 15 - 30C. This range exceeded the manufacturer's higher limit of 28C. 5. In an interview on 12/16/2025 at 2:51 pm, the Mycobacteriology Technical Supervisor confirmed the findings. F. BioRad CFX96 Polymerase Chain Reaction (PCR) system. 1. During a tour of the Special Microbiology area (Room 4108) on 12/18/2025 at 11:30 am, a BioRad CFX96 PCR instrument (Serial Numer 785BR07601) was observed and in use. 2. The manufacturer's instructions for the BioRad CFX 96 stated " ...System Requirements ...Indoor use ...Relative humidity maximum of 80%, non-condensing." 3. Review of the laboratory's environmental record for Room 4108 from January 2025 through November 2025 revealed the laboratory failed to define an acceptable relative humidity range for the room. 4. In an interview on 12/18/2025 at 12:35 pm, the Special Microbiology Technical Supervisor confirmed the findings. Word Key: MTP=Mycobacterium tuberculosis RIF=Rifampin TB=Tuberculosis
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and

	other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on observation of laboratory areas and interview with laboratory staff, the laboratory failed to ensure reagents and chemicals were labeled to indicate their identity and expiration dates for two of two years. Findings: A. Blood Lead Laboratory: 1. Observation of the blood lead laboratory on December 16, 2025, at 3: 35 pm, revealed an unlabeled tube with a red top next to the Nexion analyzer. 2. The Lead technologist confirmed on December 16, 2025, at 3:40 pm that the red top tube was Nexion standards performance solution, but the tube on the analyzer was not labeled. B. Chemisty and Hematology Laboratory: 1. Observation of the chemistry laboratory on December 17, 2025, at 12:55 pm revealed a bottle of Cargille Oil Immersion Type A that did not include an expiration date (Lot #050195, Receiver November 12, 2019, opened May 14, 2024. 2. The Chemistry supervisor confirmed on December 17, 2025, at 1:00 pm that the bottle did not include an expiration date and is used for manual differential cell reviews. C. Media Preparation Area: 1. Observation of the Media preparation room on December 18, 2025, at 1:00 pm, revealed the following chemicals were not labeled with expirations dates: a. Three of Three bottle of Fisher Bioreagents Sodium Phosphate Monobasic Monohydrate (Lot: 127924). b. Two of two bottles of Fisher Bioreagents Sodium Chloride (Lot: 211281). c. One of one bottle of Fisher Bioreagents Potassium Phosphate Monobasic (Lot: 253185). d. One of one bottle of Thermo Scientific Sodium phosphate, dibasic (Lot: B0156109A). 2. The special microbiology technical supervisor confirmed on December 18, 2025, at 1:15 pm that expiration dates were not written on all chemical stock bottles. 46043 II. Based on observation, review of manufacturer's instructions, and confirmed in staff interview, the laboratory failed to label four of four secondary containers with reagent identification information, storage requirements and expiration dates. Findings: 1. During a tour of the mycobacteriology testing area (Room 4409) on 12/16/2025 at 1:50 pm, four secondary containers were observed to be in use by the mycobacteriology department for acid fast bacterium staining. One container was labeled "Auramine O". The laboratory failed to label the container with the reagent lot number, storage requirement and expiration date. One container was labeled "Fluorescent Decolorizer". The laboratory failed to label the container with the reagent lot number, storage requirement and expiration date. One container was labeled "K Permanganate". The laboratory failed to label the container with the reagent lot number, storage requirement and expiration date. One container was not labeled with any reagent identification, lot number, storage requirement or expiration date. 2. The Aerospray TB Applications Manual (Revision 2023-04-10) stated " ... Storage and Shelf Life ...Once opened, stains are stable for 90 days ..." 3. In an interview on 12/16/2025 at 1:55 pm, the Mycobacteriology Technical Supervisor (TS) stated that three of the bottles contained Aerospray TB (Tuberculosis) reagents used for Auramine Rhodamine staining. The TS stated that the fourth container was deionized water. The Mycobacteriology TS confirmed the secondary containers were not labeled with requirement information.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: I. Based on observation and confirmed in staff interview, the laboratory failed to ensure that three of three bottles of expired reagents were not available for use. Findings: 1. During a tour of the mycobacteriology testing area (Room 4409) on 12/16 /2025 at 1:50 pm, three bottles of expired ELITech Aerospray Nozzle Cleaning Solution Concentrate (Lot number 226486; Expiration date 03/31/2023) were observed stored under the counter. 2. In an interview on 12/16/2025 at 1:55pm, the Mycobacteriology Technical Supervisor confirmed the reagent was expired. II. Based on review of laboratory quality control records and confirmed in staff interview, the laboratory failed to ensure expired ninhydrin reagent was not available for use for four of eleven testing events. Findings: 1. Review of the laboratory quality control record titled "Hippurate Hydrolysis Test Quality Control Chart" from 02/27/2023 through 10 /02/2025 revealed the reagent was used eleven times. Expired ninhydrin reagent was used for testing on the following dates: Date of test: 04/03/2023; Lot number of Ninhydrin B03D011M; Expiration date 03/31/2023 Date of test: 04/17/2023; Lot number of Ninhydrin B03D011M; Expiration date 03/31/2023 Date of test: 05/09 /2024; Lot number of Ninhydrin B05D343M; Expiration date 04/30/2024 Date of test: 06/06/2024; Lot number of Ninhydrin B05D343M; Expiration date 04/30/2024 2. In an interview on 12/18/2025 at 11:54 am, the Special Microbiology Technical Supervisor confirmed the findings and stated that proficiency testing specimens were the only samples tested on those days. III. Based on direct observation and confirmed in staff interview, the laboratory failed to ensure expired materials were not available for use for one of two McFarland Standards. Findings: 1. During a tour of the Special Microbiology area (Room 4101) on 12/18/2025 at 12:15 pm, one vial of McFarland Standard (Lot number 363322, Expiration Date 08/30/2024) was observed in use under the Nuaire Biosafety hood. 2. In an interview on 12/18/2025 at 12:20 pm, the Special Microbiology Technical Supervisor confirmed the material was expired.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 direct observation, review of manufacturer's instructions, laboratory procedure, maintenance records, and confirmed in staff interview, the laboratory failed to perform monthly maintenance per manufacturer's instructions for the Cepheid GeneXpert Infinity molecular diagnostic system for three of four months. Findings: 1. During a tour of the mycobacteriology testing area (Room 4112) on 12/16 /2025 at 2:10 pm, a Cepheid GeneXpert Infinity instrument (Serial Number 843224) was observed to be in use by the laboratory. 2. The manufacturer's instructions stated on the Cepheid GeneXpert Infinity Maintenance Log (302-1289 Rev. A April 2019) stated " ...Monthly Maintenance Vacuum rear fan filters Archive/Purge Tests ..." 3. The laboratory procedure titled "GeneXpert MTB/RIF" stated " ...Maintenance Performance Perform daily, weekly, monthly and yearly maintenance as shown in appendix 2 ..." 4. Review of the laboratory maintenance records for the Cepheid GeneXpert Infinity from July 2025 through October 2025 revealed the laboratory

	failed to perform monthly maintenance for August, September and October 2025. 5. In an interview on 12/16/2025 at 2:13pm, the Mycobacteriology Technical Supervisor confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of a complete individualized quality control plans (IQCP), and interview with special microbiology section lead, the laboratory failed to perform quality control (QC) at least once each day of patient testing for one of two Biofire Micro arrays in use. Findings: 1. The Developing an IQCP SOP (Standard Operating Procedure) stated: a. 4. Laboratory Director Responsibility: 4.1 "The Laboratory Director is responsible for ensuring that quality control and quality assessment programs are established and maintained to assure the quality of laboratory services, including the identification of failure in quality as they occur". b. 8.3 Quality Control Plan (QCP) 8.3.4.2 "Specify the number, type and frequency of testing QC material". c. 8.4 Quality Assessment. 8.4.1 "All IQCP Quality Assessment monitoring must be part pf the laboratory overall Quality Assessment plan. The laboratory must establish a review system for all ongoing monitoring of the effectiveness of their IQCP". 2. Review of the Biofire Filmarray Gastrointestinal (GI) Panel IQCP on December 17, 2025 revealed, the IQCP in use did not include a quality assessment section, did not state the frequency the laboratory performed quality control and was not signed by the pervious or current laboratory director. 3. The annual test volume for the Biofire Filmarray GI panel: 64. 4. Interview with the special microbiology section lead on December 17, 2025 at 10:15 am confirmed the IQCP in use for the Biofire Filmarray GI panel was incomplete and not signed by the laboratory director.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on lack of stain quality control (QC) records and interview with the Chemistry section lead, the laboratory failed to test hematological staining materials for their staining characteristics for two of two years (December 2023 to December 2025). Findings: 1. The laboratory was unable to provide manual differential cell review

	stains tested for their intended reactivity for two years of testing (December 2023 to December 2025). 2. On December 17, 2025, at 1:00 pm the chemistry lead confirmed the laboratory never performed QC for manual differential cell reviews.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of laboratory procedures, laboratory records, and confirmed in staff interview, the laboratory failed to check each batch of media for the ability to support growth for one of one lot number of Lowenstein Jensen media and four of four lot numbers of BACTEC mycobacteria growth indicator (MGIT) tubes. Findings: 1. The laboratory procedure titled "Growth and Detection-Solid Media and Reference Cultures" stated " ...VII. Quality Control Requirements A. Slants, Agar plates, and liquid media Upon receipt of shipment of media staff ...4. Will visually inspect each lot for obvious problems such as cracked or damaged plates, again detached from petri dishes, frozen or melted agar, unequal filling of the plates, tubes or vials, insufficient media in the plates, tubes, or vials, hemolysis of blood containing media, change in expected color, excessive bubbles or rough surfaces, excessive moisture, or dehydration, obvious contamination and presence of precipitates ..." The laboratory procedure titled "Growth and Detection-Liquid MGIT Media" stated " ...Quality Control Requirements 1. Upon receiving a new shipment of MGIT tubes lot/lots, inspect few tubes from each box for any visible contamination and tube breakage ..." The laboratory procedures failed to include checking media for the ability to support growth. 2. Review of laboratory records revealed the laboratory failed to verify or document the ability to support growth for the following media: Lowenstein-Jensen slants; Lot number 285341; Expiration date 06/20/2026 MGIT tubes: Lot number 4116300; Expiration date 10/22/2025 Lot number 5078106; Expiration date 09/23 /2026 Lot number 5093457; Expiration date 09/27/2026 Lot number 5182229; Expiration date 12/27/2026 3. In an interview on 12/16/2025 at 2:31 pm, the Mycobacteriology Technical Supervisor (TS) was asked if the laboratory had an IQCP (Individualized Quality Control Plan) for the media used in mycobacteriology. The TS stated they did not have an IQCP. This confirmed the findings. II. Based on review of laboratory procedure, the laboratory's IQCP for commercially prepared media, media quality control records, and confirmed in staff interview, the laboratory failed to check each batch of media for the ability to support growth for two of two lots numbers of Selenite Broth, two of two lot numbers of Acetate Differential agar, and one of two lot numbers of Campylobacter Selective media. Findings: 1. The laboratory procedure titled "Microbial Media QA Procedures" stated " ...General Procedure for Commercial Media ...An approved Individualized Quality Assurance Plan (IQCP) is in place for Commercially Prepared 'CLSI Exempt' Media used by the Special Microbiology Section of the Mississippi Public Health Laboratory ... 2. The IQCP titled "IQCP for Commercially Prepared CLSI Exempt Media (Signed by the previous laboratory director on 12/20/2015) listed 56 types of commercial media covered under the laboratory's IQCP. The document did not list Selenite broth, Acetate Differential agar,

	or Campylobacter Selective media. 3. The laboratory procedure titled "Microbial Media QA" stated " ...6. For nonexempt media the user will 6.1 Verify and document acceptable growth and./or inhibitory properties with appropriate bacterial and fungal control organisms ..." 4. Review of the laboratory's media quality control records revealed the following: a. Selenite Broth; Lot number 210385, Expiration date 06/08 /2025 received by the laboratory on 12/27/2024. Selenite Broth; Lot number 268473, Expiration date 11/03/2025 received by the laboratory on 06/17/2025. b. Acetate Differential agar; Lot number 801390, Expiration date 02/11/2025 received by the laboratory on 04/02/2024. Acetate Differential agar; Lot number 190486, Expiration date 10/22/2025 received by the laboratory on 12/27/2024. c. Campylobacter Selective media; Lot number 291400, Expiration date 09/16/2025 received by the laboratory on 08/13/2025. Further review of the laboratory's media quality control records revealed the last date Selenite broth was quality controlled with appropriate bacterial organisms was 10/26/2023 and the last date Campylobacter Select media was quality controlled was 01/03/2025. 5. In an interview on 12/18/2025 at 12:11 pm, the Special Microbiology supervisor was asked to provide documentation of media quality control to include the ability to support growth for Selenite broth, Acetate Differential agar, and Campylobacter Selective media. No documentation was provided. This confirmed the findings. Word Key: CLSI=Clinical and Laboratory Standards Institute QA=Quality Assurance
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a)(2) Each week of use for Gram stains. This STANDARD is not met as evidenced by: Based on observation, review of laboratory procedure, quality control (QC) records, and confirmed in staff interview, the laboratory failed to perform weekly Gram Stain quality control testing for 90 of 91 weeks in 2024 and 2025. Findings: 1. During a tour of the special microbiology area on 12/18/2025 at 11:30 am, one bottle each of Remel Gram Crystal Violet, Gram Decolorizer, Gram Iodine, and Gram Safranin were observed open and in use by the laboratory. 2. The laboratory's procedure titled "Gram Stain" stated " ...Quality Control Requirements Quality Control is performed weekly and/or when a new lot of reagent is put into use ..." 3. Review of the laboratory's quality control record titled "Gram Stain Control Chart" from 01/06/02024 through 12 /16/2025 revealed the laboratory performed weekly gram stain QC on 01/06/2024. The laboratory documented the next weekly gram stain performance on 10/15/2025 and then weekly thereafter through 12/16/2025. 4. In an interview on 12/18/2025 at 11: 55 am, the Special Microbiology Technical Supervisor confirmed the findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation of the special microbiology laboratory, the lack of records and

	interview with special microbiology section lead, the laboratory failed to perform comparison on two of two Biofire Filmarray used to perform the Gastrointestinal (GI) Panel. Findings: 1. Tour of the Special microbiology laboratory on December 17, 2025 10:00 am revealed two Biofire Filmarray instrument were stacked one on top of the other (S/N - 2FA05284 and S/N -2FA09220) used with the GI Panel. 2. The laboratory was unable to provided comparison studies performed for both of the Biofire Filmarray as they both run the GI panel. 3. The annual test volume for the Biofire Filmarray GI panel: 64. 4. Interview with the special microbiology section lead on December 17, 2025 at 10:20 am confirmed comparison studies were not performed on the two Biofire Micro arrays used to perform the Gastrointestinal (GI) Panel.
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: I. Based on review of laboratory procedures, quality control (QC) records, and interview with the Chemistry team lead, the laboratory failed to document corrective action non-conforming events when QC errors flagged on one of one DiaSorin Liaison XL from July 2024, to December 17, 2025. Findings: 1. The MS Public Health Laboratory Clinical Services Quality Management Systems procedure, 12.2 Corrective Action states, "All nonconforming events are recorded, tracked trends identified, and root cause analysis performed". 2. Review of the one DiaSorin Liaison XL QC records for the Interferon Gamma Release test revealed flagged error for Westgard rules broken on the following days of testing: a. July 12, 2024, to August 8, 2024 - Level 1 and Level 2. b. June 12, 2024, to July 1, 2024 - Level 1 and Level 2. c. September 11, 2024, to October 1, 2024 - Level 2. d. September 17, 2024 - Level 1. e. December 23, 2024 - Level 2. f. March 21, 2025, to April 1, 2025 - Level 2. g. March 29, 2025, and April 1, 2025 - Level 1. h. April 24, 2025, to April 30, 2025 - Level 2. i. November 26, 2025, to December 17, 2025 - Level 1. 3. The laboratory failed to follow their procedure and document nonconforming events performed for QC failures. 4. The laboratory performed 2,647 Interferon Gamma Release test on the DiaSorin Liaison XL from July 2024 to December 17, 2025. 5. The chemistry laboratory lead confirmed the above finding on December 17, 2025 at 12:30 pm. 38798 II. Based on review of room temperature (RT) records, corrective action record PS0-52, and interview with the Immunology Technical Supervisor (ITS), the laboratory failed to document corrective actions taken when the RT fell below the laboratory defined acceptable temperature limit for 3 out of 240 testing days in room number 3401. Findings: 1. A review of the room temperature records from 01/02/2025 to 12/17/2025 for room number 3401, revealed the following: Acceptable Room Temperature Range = 20C to 25C Notation: Circle any unacceptable readings in red and record corrective action on PS0-52. Date Room Temperature Recorded 05/20

	/2025 17.5C 05/27/2025 19.0C 12/15/2025 18.4C 2. A request for Forms PS0-52 documenting corrective actions taken for the dates indicated above for room temperatures out of acceptable limits, resulted in no documentation of corrective actions. 3. In an interview on 12/17/2025 at approximately 11:45 AM, the ITS confirmed there were three dates for room number 3401 where the room temperature fell below the acceptable limit of 20C and no corrective actions were documented using the Form PS0-52.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) procedures, and interview with the Clinical Quality Assurance Officer, the laboratory failed to establish a complete QA procedure to include monthly QA indicators reviewed for two of two years. Findings: 1. The MS Public Health Laboratory Clinical Services Quality Management Systems procedure, 13.2 Quality Indicators states, "The laboratory establishes quality indicators to monitor and evaluate performance of it process every month. List here the quality indicators." 2. Review of the procedure on December 17, 2025, revealed the laboratory failed to list their quality indicators reviewed every month in the procedure for two years. 3. The Clinical Quality Assurance Officer confirmed the findings above on December 17, 2025, at 12:00 pm.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory Quality Assurance policies, the laboratory's IQCP for commercially prepared media, Special Microbiology procedure manuals, and confirmed in staff interview, the laboratory's analytic quality assurance assessment review failed to ensure the laboratory's IQCP for commercial media was reviewed annually and failed to ensure procedures for testing no longer performed were removed from the testing areas. Findings: 1. The laboratory policy titled "Developing an IQCP" stated " ...8.4 Quality Assessment ...8.4.3 The IQCP must be review annually ..." 2. Review of the laboratory's IQCP titled "IQCP for Commercially Prepared CLSI Exempt Media" revealed the document was signed by the previous laboratory director on 12/20/2015. No annual review was provided per laboratory policy, and the document was not signed by the current laboratory director. 3. The laboratory policy titled "Technical Procedure Manuals/Document Control" stated " ... 6.2 Document Control ...6.5 Retirement of a testing process SOPs requires the written Technical Procedure for testing no longer performed be officially retired. It is the

	responsibility of the Document Controller to assure that the obsolete copy is officially retired and has been removed from the testing areas ..." 4. Review of the Special Microbiology test procedure manuals revealed the following tests that were no longer performed by the laboratory but were still available in the testing areas: Laboratory Manual "Miscellaneous Logsheets & Procedures" Test no longer performed: Haemophilus X,V,XV Strips Differentiation of Haemophilus Neisseria Identification N. meningitidis Antisera QC Procedure Laboratory Manual "Rapid Identification Systems Procedures" Tests no longer performed: API Coryne (Analytical Profile Index) Crystal Gram Positive Identification Rapid NH (Neisseria and Haemophilus) Laboratory Manual "General Testing" Tests no longer performed: Coagulase D-Test ESBL (Extended Spectrum Beta Lactamase) TSI (Triple Sugar Iron) 5. In an interview on 12/18/2025 at 9:15 am, the Special Microbiology Technical Supervisor confirmed that the laboratory no longer performed the tests listed above. Word Key: SOP=Standard Operating Procedure
D5815	TEST REPORT CFR(s): 493.1291(h) (h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on observation during a laboratory tour, review of the laboratory client services manual, electronic mail (email) correspondences, and interview with the Immunology Technical Supervisor (ITS), the laboratory failed to notify clients of a delay in testing for 2171 of 2171 test specimens received from 11/19/2025 to 12/17/2025. Findings: 1. During a tour of the Immunology/STD laboratory the following was observed in the accessioning room adjacent to room number 3304: 2. Stored in specimen racks on counter tops in an open room were the following: Chlamydia trachomatis/Neisseria gonorrhea (CT/GC) specimen pending testing = 1784. Trichomonas Vaginalis (TV) specimen pending testing = 387 Specimen collection dates ranged from 11/19/2025 to 12/17/2025. Random sampling of CT/GC/TV pending testing: Medical Record Number (MRN): 1031194 Collection Date (CD): 11/25/2025 MRN: 2646966 MRN: 3023634 CD: 11/24/2025 CD: 11/25/2025 MRN: 4648167 MRN: 4401168 CD: 11/25 /2025 CD: 11/25/2025 MRN: 2398399 MRN: 2520338 CD: 11/24/2025 CD: 12/01 /2025 MRN: 2614993 MRN: 1293914 CD: 11/26/2025 CD: 12/01/2025 MRN: 3014621 CD: 11/26/2025 3. A review of the Mississippi Public Health Laboratory Client Services manual, revised March 2023, revealed the following: CT/GC/TV Nucleic Acid Amplification Test (NAAT) Storage Instructions: Samples in transport tubes may be kept at room temperature for up to 30 days. Turnaround time: 5 to 10 business days 4. A review of four email correspondences from 11/19/2025 to 12/17 /2025 between the ITS and the Chief Nursing Officer, Mississippi State Department of Health Field Services reveal no official notice was sent to clients from the laboratory for delay in specimen testing for CT/GC/TV. 5. In an interview on 12/18 /2025 at approximately 3:00 PM, the ITS confirmed there were 1784 CT/GC and 387 TV specimen (2171 total) pending testing with collection dates from 11/19/2025 to 12 /17/2025, and that no notifications had been sent out to clients for delay in testing specimen.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manuals, manufacturer's instructions, laboratory records, patient records, and staff interviews, the Laboratory Director failed to provide overall management and direction for the laboratory in accordance with 493.1445. Findings: 1. The Laboratory Director failed to ensure all proficiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's performance. Refer to D6091. 2. The Laboratory Director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services. Refer to D6094. 3. The Laboratory Director failed to ensure the maintenance of acceptable levels of analytical performance for each test system. Refer to D6095. 4. The Laboratory Director failed to ensure all necessary corrective actions and non conforming events are documented. Refer to D6096.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, manufacturer's instructions, laboratory records, patient records, and staff interviews, the Laboratory Director failed to ensure all proficiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's performance. Findings: 1. The Laboratory Director failed to ensure all proficiency testing attestation forms were signed by the appropriate personnel. Refer to D2009.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, manufacturer's instructions, laboratory records, patient records, and staff interviews, the Laboratory Director failed to ensure quality control (QC) and quality assessment (QA) programs are maintained to assure the quality of laboratory services. Findings: 1. The Laboratory Director failed to ensure the performance of QC at least once each day of patient testing for Biofire Micro arrays in use. Refer to D5445. 2. The Laboratory Director failed to ensure the performance of hematological staining materials for their staining characteristics. Refer to D5473. 3. The Laboratory Director failed to ensure each batch of media for the ability to support growth for microbiology growth media. Refer

	to D5477 I and II. 4. The Laboratory Director failed to ensure a complete QA procedure was established to include monthly QA indicators. Refer to D5971. 5. The Laboratory Director failed to ensure the laboratory's IQCP for commercial media was reviewed annually and failed to ensure procedures for testing no longer performed were removed from the testing areas. Refer to D5793. 6. The Laboratory Director failed to ensure quality control procedures for manual differential cell review were established. Refer to D5403.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, manufacturer's instructions, laboratory records, patient records, and staff interviews, the Laboratory Director failed ensure the maintenance of analytical performance for each test system. Findings: 1. The Laboratory Director failed to ensure acceptable room temperatures and/or humidity ranges monitored were consistent manufacturer's requirements. Refer to D5413, I, II, III, IV, V, VI, VII, VIII, IX. 2. The Laboratory Director failed to ensure secondary containers with reagent identification information, storage requirements and expiration dates were labeled. Refer to D5415, I and II. 3. The Laboratory Director failed to ensure expired reagents were not available for use. Refer to D5417, I, II, and III. 4. The Laboratory Director failed to ensure monthly maintenance per manufacturer's instructions for the Cepheid GeneXpert Infinity molecular diagnostic system were performed. Refer to D5429. 5. The Laboratory Director failed ensure comparisons on the Biofire Filmarray used to perform the Gastrointestinal (GI) Panel were performed. Refer to D5775.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals, manufacturer's instructions, laboratory records, patient records, and staff interviews, the Laboratory Director failed to ensure all necessary corrective actions and non conforming events were documented. Findings: 1. The Laboratory Director failed to ensure all necessary corrective actions and non conforming events were documented. Refer to D5781, I and II.