Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	11D0671793	08/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Georgia Public Health Laboratory	1749 Clairmont Road, Decatur, GA	
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	A recertification survey was conducted from 08/21/2023 through 08/25/2023. Standard level deficiencies were cited.
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 the laboratory test list, laboratory proficiency testing (PT) records and confirmed in interview with the Laboratory Quality Manager, revealed the laboratory failed to perform twice annual accuracy assessments for Hepatitis A IgM antibody (HAVM) testing for 2 of 2 years (2021 and 2022). Findings included: 1. Review of the laboratory's submitted test list revealed the laboratory tested specimens for Hepatitis A IgM antibodies. 2. Review of the laboratory's proficiency testing and twice annual accuracy assessment records for 2021 and 2022 revealed no documentation of twice annual accuracy assessment for HAVM. 3. In an interview on 08/23/2023 at 11:27 AM, the Laboratory Quality Manager confirmed that the laboratory failed to perform twice annual accuracy assessment for HAVM.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, laboratory policy, patient records, and confirmed in staff interview, the laboratory failed to follow written policies and procedures for preanalytical requirements for the Hologic Aptima Trichomonas Vaginalis Assay, the Hologic Aptima Combo 2 Chlamydia-Gonorrhea Assay, and the Aptima Herpes Simplex Viruses 1 and 2 Assay for 82 of 82 patient specimens. Findings included: 1. On 08/22/2023 at 12:05 PM and 2:30 PM the delivery of patient specimens to the laboratory was observed. Multiple specimens from an individual location or clinic were submitted in one biohazard bag. From the receiving area, the patient specimens were transported to the accessioning area where biohazard bags were opened, and specimens were sorted according to tests requested. During the accessioning process, multiple patients with multiple Aptima specimens' tubes in the same biohazard bag were observed in direct contact with each other. Eighty-two Aptima specimen containers were processed. 2. The manufacturer's instructions revealed the following: a. Aptima Trichomonas vaginalis Assay (503684 Rev. 008) stated, " ...Warnings and Precautions ...Specimen Related ...I. Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen containers do not contact one another ..." b. Aptima Combo 2 Assay (AW-20535-001 Rev. 004) stated, " ...Warnings and Precautions ...Specimen Related ...M. Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen containers do not contact one another ..." c. Aptima Herpes Simplex Virus 1&2 Assay (AW-15636 Rev. 005) stated, " ...Warnings and Precautions ... Specimen Related ...I. Avoid cross-contamination during the specimen handling steps. Be especially careful to avoid contamination by the spread of aerosols when loosening or uncapping specimens. Specimens can contain extremely high levels of virus. Ensure that specimen containers do not contact one another ..." 3. The laboratory policies stated the following: a. MVI-VI 6 Hologic Aptima Trichomonas vaginalis Assay (Approved by the laboratory director 12/31/2022) stated, " ...5.4 Specimen-related precautions: ...5.4.3 Avoid cross-contamination while handling specimens. Specimens may contain extremely high levels of organisms. Therefore, ensure that specimen containers do not contact one another ..." b. MVI-VI 7 Hologic Aptima Combo 2 Assay Chlamydia-Gonorrhea (Approved by the laboratory director) stated, " ...5.4 Specimen-related precautions: ...5.4.4 Avoid cross-contamination while handling specimens. Specimens may contain extremely high levels of organisms. Therefore, ensure that specimen containers do not contact one another ..." c. MVI-VI 18 Aptima Herpes Simplex Virus 1&2 Assay (Approved by the laboratory director 12 /31/2022) stated, " ...5.0 Special Safety Precautions ...5.8 Avoid cross-contamination during the specimen handling steps. Be especially careful to avoid contamination by the spread of aerosols when loosening or uncapping specimens. Specimens can contain extremely high levels of organisms. Ensure that specimen containers do not contact one another ..." 4. A random review of records of the 82 patient specimens received 08/22/2023 revealed the following patient specimens were tested and reported by the laboratory: Patient 24B0004651; Specimen: Urine; Aptima Combo-2 Assay Patient 24B0004655; Specimen: Urine; Aptima Combo-2 Assay Patient 24X1233019; Specimen: Urine; Aptima Combo-2 Assay Patient 24X1233088; Specimen: Urine; Aptima Combo-2 Assay Patient 24X1229085; Specimen: Urine; Aptima Combo-2 Assay Patient 24X1233048; Specimen: Swab; Aptima Combo-2 Assay Patient 24X1233113; Specimen: Swab; Aptima Combo-2 Assay Patient 24X1230047; Specimen: Swab; Aptima Combo-2 Assay 5. In an interview on 08/23 /2023 at 1:55 PM, the Laboratory Director and the Laboratory Quality Manager

	confirmed that the laboratory failed to ensure specimen containers did not contact one another.
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: I. Based on review of laboratory procedure manuals, the laboratory's online Laboratory Services Index and interview with staff, the laboratory failed to include specimen storage and transport conditions in their procedure manual or failed to include specimen storage and transport conditions in their procedure manual that were consistent with the online Laboratory Services Index. Findings included: Below is a sampling of review of the laboratory's procedure manual and online Laboratory Services Index. 1. Neisseria Meningitidis and Haemophilus Influenzae by RT-PCR a. The procedure named "MMB-BA 5 Neisseria Meningitidis and Haemophilus Influenzae by RT-PCR" stated: "4.3 Specimen handling 4.3.1 Care must be taken to ensure that samples are kept cold during storage and shipment." The procedure does not define a temperature range for "cold" nor a timeframe for shipping the specimen. b. The online Laboratory Services Index stated under "Special Bacteriology" the following: "Storage/Transport Cultures can be maintained at room temperature (15-30C) during transit as soon as possible after collection." A timeframe for shipping the specimen is not included in the instructions. c. During interview on 8/23/2023 at 11 AM, the Laboratory Director confirmed the above discrepancies in the MMB-BA 5 Neisseria Meningitidis and Haemophilus Influenzae by RT-PCR procedure and the Laboratory Services Index. 2. B. pertussis & B. parapertussis Culture and DFA a. The procedure named "MMB-BA 11 B. pertussis & B. parapertussis Culture and DFA" does not include specimen transport requirements. b. The online Laboratory Services Index stated under "Bordetella Pertussis Culture" the following: "Storage/Transport Swab: Regan Lowe semisolid transport medium tube is recommended. Ship specimen at room temperature (15-30 C). If a shipping delay is anticipated, use the refrigerated (2-8 C) shipping outfit. Culture: Isolates must be shipped using ambient (15-30 C) specimen outfit within 24 hours." c. During interview on 8/23/2023 at 11 AM, the Laboratory Director confirmed the above discrepancies in the MMB-BA 11 B. pertussis & B. parapertussis Culture and DFA procedure and the Laboratory Services

	Index. II. Based on review of the Biofire FilmArray Gastrointestinal (GI) Panel procedure, review of the laboratory's Individualized Quality Control Plan (IQCP) and review of the online Laboratory Services Index, the laboratory failed to include specimen transport requirements and the number, type and frequency of external quality control materials in the Biofire GI Panel procedure. Findings included: 1. Specimen Transport Conditions a. Review of the Biofire FilmArray Gastrointestinal (GI) Panel procedure (procedure code unknown) found the procedure did not include conditions for specimen transport. b. The online Laboratory Services Index stated under "FilmArray GI Panel" the following: "Storage/Transport Feces for enteric pathogens be maintained at room temperature (15-30C) during transit." No timeframe for transport is indicated. 2. External Quality Control a. Review of the Biofire FilmArray Gastrointestinal (GI) Panel procedure (procedure code unknown) found the procedure failed to include the number, type and frequency of performing external quality control materials. b. Review of the laboratory's IQCP for the Biofire FilmArray Gastrointestinal (GI) Panel found the laboratory's Quality Control Plan included testing one of two external positive control materials each day of patient testing. The two external positive control materials are tested on a rotating basis.
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: I. Based on direct observation, review of manufacturer's instructions, environmental records (01/2023-07/2023), and in interview with the Director of Microbiology, the laboratory failed to ensure the room temperature and relative humidity (RH) was within manufacturer's specifications for the BacTec MGIT 960 automated mycobacterial detection system for 7 of 7 months in 2023. Findings included: 1. During a tour of the mycobacteriology area on 08/22/2023 at 12:45 PM, two BacTec MGIT 960 instruments (Serial Numbers MG0256 and MG0254) and one Cepheid GeneXpert (Serial Number 7077559) were observed in use. 2. Review of the manufacturer's instructions revealed the following environmental specifications: BacTec MGIT 960 (May 1999, Document Number: MA-0117, Revision C) stated, "Environmental Requirements Operating Conditions Temperature 19C - 30C (66.2F - 86F) Microbiological efficacy may be compromised above 32C. Humidity 30%-80% RH." 3. Review of the laboratory's environmental records from January 2023 through July 2023 revealed the laboratory failed to monitor and document the room temperature and relative humidity for the area housing the two BacTec MGIT 960 instruments. 4. During an interview on 08/22/2023 at 12:50 PM, the mycobacteriology Technical Supervisor stated that the room temperature and relative humidity were not monitored in the area. This confirmed the findings. II. Based on direct observation, review of manufacturer's instructions, environmental records (01/2023-07/2023), and in interview with the Director of Microbiology, the laboratory failed to ensure the room temperature was within manufacturer's specifications for the Cepheid GeneXpert MTB/RIF reagent for 7 of 7 months in 2023. Findings included: 1. During

	a tour of the mycobacteriology area on 08/22/2023 at 12:45 PM, the following reagents were observed stored in the processing room in the mycobacteriology testing area: Three boxes Xpert MTB/RIF Assay Lot Number 100863461; Expiration Date 03/30/2025 2. The manufacturer's instructions for the Xpert MTB/RIF assay (301-1404, Rev G July 2020) stated, " ...Storage and Handling Store the Xpert MTB/RIF Assay cartridges and reagents at 2 -28 C ..." 3. Review of the laboratory's environmental records from January 2023 through July 2023 revealed the laboratory failed to monitor and document the room temperature in the processing room. 4. During an interview on 08/22/2023 at 12:50 PM, the mycobacteriology Technical Supervisor stated that the room temperature was not monitored in the processing area. This confirmed the findings. III. Based on direct observation, review of manufacturer's instructions, environmental records (01/2023-07/2023), and in interview with the immunology Technical Supervisor, the laboratory failed to ensure relative humidity was within manufacturer's specifications for the Diasorin Liaison XL automated chemiluminescence analyzer for 7 of 7 months in 2023. Findings included: 1. During a tour of the immunology area on 08/24/2023 at 11:45 AM, two Diasorin Liaison XL automated chemiluminescence analyzers (Serial Numbers 221005151 and 2210006200) were observed in use. 2. Review of the manufacturer's instructions revealed the following environmental specifications: Diasorin Liaison XL (en-US-Revision G, 11-209) stated, " ...10.7 Environmental Conditions ...Humidity: Operating: 10 - 85% non-condensing ..." 3. Review of the laboratory's environmental records from January 2023 through July 2023 revealed the laboratory failed to monitor and document humidity in this area. 4. During an interview on 08/24/2023 at 12:04 PM, the immunology Technical Supervisor stated that humidity was not monitored in the area. This confirmed the findings. 27526 IV. Based on observation and interview with staff, the laboratory failed to monitor the humidity in the MiSeq Room of the laboratory. Findings included: During tour of the MiSeq area of the laboratory on August 24, 2023 at 10 AM, two Illumina MiSeq analyzers were noted, serial #M05813 and serial #M70384. No thermometer or hygrometer were observed in the area. During interview on August 24, 2023 at 10:27 AM, the Quality Assurance Fellow confirmed the laboratory's biomedical staff monitored the temperature in the MiSeq area, but the humidity was not monitored. Review of the MiSeq System operators manual states the following: "Humidity ... Operating Conditions: 30-75% relative humidity (non-condensing)"
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: I. Based on direct observation, manufacturer's instructions and confirmed in an interview with staff, the laboratory failed to ensure 17 of 17 observed expired supplies were not available for use. Findings included: 1.During a tour of the facility on 8/25/23 at 9:30 a.m., on the second floor hallway of the facility, the inspector observed 8 boxes of BioHit Safety Space Filter Tips and 9 bottles of Gibco Phosphate Buffered Saline on the supply cart shelves: 8 boxes BioHit Safety Space Filter Tips - Lot number 3939103111F; expiration date 11/2014 Lot number 393912101F; expiration date 12/2014 Lot number 101102393F; expiration date 11/2015 9 bottles of Gibco Phosphate Buffered Saline - Lot number 2178391; expiration date 03/31/2022 2.

	During an interview on 8/25/23 at 9:34 a.m., on the second floor hallway of the facility, the Quality Improvement Consultant acknowledged the supplies were expired. This confirmed the above findings. 27526 II. Based on observations during the tour of the laboratory and interview with the Microbiology Technical Supervisor (TS), the laboratory used expired culture media. Findings included: 1. During the tour of the Microbiology section of the laboratory on August 23, 2023 at 3:10 PM, expired culture media to include Sheep Blood Agar plates (BAP) and Chocolate Agar plates (CAP) was observed in use at work stations. Observation of the Microbiology walk in refrigerator on August 23, 2023 at 3:20 PM found the following expired culture media available for use: BBL Hektoen Enteric Agar, Lot #3123248, Expiration date 08/07 /2023 - 5 cases Remel BAP, Lot #636960, Expiration date 05/13/2023 - 1 case Remel Charcoal Blood Agar, Lot #648130, Expiration date 05/16/2023 - 15 boxes Remel CAP, Lot #655377, Expiration date 06/21/2023 - 4 cases 2. On August 23, 2023 at 3: 10 PM, the Microbiology TS confirmed the laboratory was using expired culture media.
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: I. Based on review of manufacturer's instructions, laboratory maintenance records (January 2022 - July 2023) and interview with the Director of Microbiology, the laboratory failed to have documentation of performing weekly maintenance for 31 of 76 weeks and monthly maintenance for 19 of 19 months for the Cepheid GeneXpert system. Findings included: 1. The manufacturer's instructions for the Cepheid GeneXpert (301-0748 Rev B December 2014) listed the following maintenance requirements: "Weekly Maintenance Power down the GeneXpert instrument Power down the GeneXpert computer Monthly Maintenance Archive tests Delete tests Replace Fan Filters" 2. Review of the laboratory's maintenance record titled, "GeneXpert System Maintenance Log" from January 2022 through July 2023 revealed the laboratory failed to document the following weekly maintenance for the Cepheid GeneXpert (Serial Number 7077559): 2022 January 10 -14; January 24 - 28; March 7 - 11; April 11 - 15; May 30 - June 2; June 13 -17; August 1 - 5; August 8 - 12; September 5 - 9; September 12 - 16; September 19 - 23; September 26 - 30; October 3 - 7; October 17 - 21; October 24 - 28; October 31 - November 4; November 7 - 11; November 14 - 18; November 21 - 25; December 5 - 9; December 12 - 16; December 19 - 23 2023 January 9 - 13; January 23 - 27; February 20 - 24; March 20 - 24; March 27 - 31; April 3 - 7; April 10 - 14; June 19 - 23; June 26 - 30 Further review of the laboratory maintenance records revealed the laboratory failed to document the following monthly maintenance: January 2022; February 2022; March 2022; April 2022; May 2022; June 2022; July 2022; August 2022; September 2022; October 2022; November 2022 (Replace fan filters); December 2022; January 2023; February 2023; March 2023; April 2023; May 2023; June 2023; July 2023 3. In an interview on 08/23 /2023 at 9:50 AM, the Director of Microbiology, after review of the maintenance records, confirmed the findings. 27526 II. Based on observation, interview with Microbiology TS and lack of documentation, the laboratory failed to perform maintenance for two Eppendorf Mastercycler X50 thermocyclers. Findings included: On August 23, 2023 at 3:20 PM, two Eppendorf Mastercycler X50 thermocyclers

	were observed in the Whole Genome Sequencing (WGS) area of the laboratory. During interview on August 23,2023 at 3:20 PM, the Microbiology TS stated the Mastercycler X50 thermocyclers were currently in use but the laboratory had no maintenance records, preventative maintenance records or service records for the two thermocyclers. Review of the operator instructions for the Eppendorf Mastercycler X50 thermocyclers indicated maintenance included software updates and cleaning of various parts of the thermocyclers.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Media Quality Control forms (12/29/2021 through 08/16/2023), and interview with the Director of Microbiology, revealed that the laboratory failed to check each new lot number or new shipment of Lowenstein-Jensen testing media for its ability to support growth for six of six lot numbers. Findings included: 1. Review of the laboratory quality control form titled, "Lowenstein-Jensen Slant" revealed the laboratory failed to check each new lot number or new shipment of Lowenstein-Jensen testing media for its ability to support growth for the following lot numbers: Lot number 411543; Expiration Date 12/07/2022; Received 12/29/2021. Lot number 487044; Expiration Date 05/03/2023; Received 06/21/2022. Lot number 487779; Expiration Date 05/05/2023; Received 06/21/2022. Lot number 520369; Expiration Date 07/07/2023; Received 08/16/2022. Lot number 540246; Expiration Date 08/16/2023; Received 09/30/2022. Lot number 572818; Expiration Date 10/19/2023; Received 12/20/2022. 2. In an interview on 08/23/2023 at 9:51 AM in the conference room, the Director of Microbiology was asked if the laboratory tested the Lowenstein-Jensen media with quality control organisms to verify its ability to support growth. He stated that the laboratory did not test the media to support growth. This confirmed the findings.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by:

	Based on review of laboratory policy, laboratory quality control records, and interview with the Director of Microbiology, the laboratory failed to document the zone diameter of inhibition for antimicrobial control organisms to ensure results were within established limits for the Modified Carbapenem Inactivation Method (mCIM) procedure for 69 of 69 days of patient testing. Findings included: 1. The laboratory procedure titled, "MMB-TB 12 Modified Carbapenem Inactivation Method Procedure", stated, ..."6.0 Quality Control 6.1 Run positive and negative QC organisms on each day of testing ...6.4 For testing Enterobacteriaceae: Positive Control: Klebsiella pneumoniae (blaKPC-positive) ATCC BAA-1705 (1 uL loop of inoculum); MEM zone diameter of inhibition 6-15 mm Negative Control: Klebsiella pneumoniae (blaKPC-negative) ATCC BAA-1706 (1 uL loop of inoculum); MEM zone diameter of inhibition >/=19 mm ..." 2. Review of the laboratory record titled, "Quality Control Form for mCIM Test" from 11/16/2022 through 08/17/2023, revealed the laboratory documented quality control for Klebsiella pneumoniae ATCC 1705 and Klebsiella pneumoniae ATCC 1706 with a check mark. The laboratory failed to document the zone diameter of inhibition for the quality control organisms. 3. In an interview on 08/22/2023 at 1:25 PM in the conference room, the Director of Microbiology was asked if the laboratory documented the zone diameter for the mCIM test quality control testing. He stated that the laboratory did not document this result. This confirmed the findings. Word Key: MEM=Meropenem disk ATCC=American Type Culture Collection
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: I. Based on review of comparison test records and interview with the laboratory staff, the laboratory failed to review and sign their test results from 4 different instruments twice a year from 2021, 2022 and once in 2023. The laboratory failed to perform twice a year comparison evaluation for TREC, Quant Studio 6 Flex PCR in 2022. Findings included: 1. Review of the Newborn Screening Comparison Test results for TREC performed on the Quant Studio 6 Flex PCR in 2021, 2022, and 2023 revealed the laboratory technical supervisor (TS) did not review or sign the TREC comparison test report for 4 instruments. The laboratory did not have a space on the report for the TS to review, date and sign the test results. The laboratory performed approximately 147,000 TREC tests between 2021 - 2023. 2. Review of the laboratory procedure Quality Assurance Manual revealed on page 30-31, "Comparative Performance a. When the same test...must twice per year assess and define any variability between, assays, methods, or instrumentation. and e. All results of the comparative performance will be maintained in the testing units and will be reviewed and signed by the technical supervisor". 3. The laboratory performed TREC on 4 Quant Studio 6 Flex PCR instruments for the comparison test on April 19, 2021, October 13, 2022, February 2, 2023, and August 23, 2023. The laboratory failed to perform two comparison tests in 2022. 4. Interview with the laboratory director in the conference room on August 23, 2023 at 1:00PM, confirmed the laboratory did not have documentation of reviewed and signed TREC comparison testing reports for 2021,

	2022, and 2023 or completion twice for 2022. 46043 II. Based on review of the laboratory's policy, direct observation, review of the laboratory's records, and staff interview with the Director of Microbiology, revealed the laboratory failed to have documentation of two instrument comparisons for the Bactec MGIT 960 automated mycobacterial detection system for 2 of 2 years (2021 and 2022). Findings included: 1. The laboratory policy titled, "QAP 1 Georgia Public Health Laboratory Quality Assessment Plan", stated " ...5. Comparative Performance a. When the same test using different methodologies or instruments is performed within the GPHL, the unit reporting the assay must twice per year assess and define any variability between assays, methods, or instrumentation ..." 2. During a tour of the mycobacteriology area on 08/22/2023 at 12:45 PM, two BacTec MGIT 960 automated mycobacterial detection instruments were observered (Serial Numbers MG0256 and MG0254) were observed in use by the laboratory. 3. Review of the laboratory record titled, "BacTec MGIT 960 Instrument Comparative Study" revealed the laboratory performed one instrument comparison in 2021 (Incubation start date: 05/21/2021) and one comparison in 2022 (Incubation start date: 05/24/2022). 4. In an interview on 08/23 /2023 at 9:51 AM in the conference room, the Director of Microbiology was asked to provide documentation of a second MGIT 960 instrument comparison in 2021 and 2022. No documentation was provided. This confirmed the findings. Word Key: GPHL=Georgia Public Health Laboratory 27526 III. Based on record review and interview with staff, the laboratory failed to perform twice a year comparisons of the ABI Dx 7500 thermocyclers located in the Molecular/BT area of the laboratory. Findings included: 1. Review of Bi-Annual Instrument Comparison records for years 2021 and 2022 found the Molecular/BT area of the laboratory used seven ABI Dx 7500 thermocyclers with the following serial numbers: Dx1 serial #275011505 Dx2 serial #275012314 Dx3 serial #275030835 Dx4 serial #275011310 Dx5 serial #275030098 Dx6 serial #275031147 Dx7 serial #275030096 2. Further review of the Bi-Annual Instrument Comparison records for years 2021 and 2022 found the laboratory performed comparisons of the seven ABI Dx 7500 thermocyclers on 09/21 /2021 and again on 9/12/2022 and 09/27/2022. The laboratory failed to perform two instrument comparisons for the seven ABI Dx 7500 thermocyclers in 2022. 3. The Molecular/BT TS confirmed the above findings during interview on August 25, 2023 at 9:23 AM.
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 temperature record review and interview with laboratory staff, the laboratory failed to document corrective action for 30 of 79 temperatures out of range from May 7, 2023 - August 23, 2023. Findings Included: 1. Review of the Newborn Screening Refrigerator/Freezer temperature chart for HGB Bench temperature results

	documented from May 7, 2023 - August 23, 2023 found 30 of 79 daily temperature checks were out of range for the refrigerator (serial number SYM 4A412 16044 1405) in room 2124. A review of the laboratory acceptable refrigerator temperature range is 2 - 8 C. The laboratory installed a new thermometer in the refrigerator on May 3, 2023. 2. The laboratory Quality Assessment Manual procedure, "G. Equipment Maintenance and Function Checks, stated, "When any piece of equipment is out of range, appropriate actions is taken by the unit responsible". The laboratory failed to document any corrective actions for the temperature failures: 1. 5/07/2023 - 0.1 C. 2. 5 /09/2023 - 0.6 C. 3. 5/11/2023 - 1.2 C. 4. 5/30/2023 - 0.3 C. 5. 6/01/2023 - 1.0 C. 6. 6 /15/2023 - 0.9 C. 7. 6/16/2023 - 0.1 C. 8. 6/09/2023 - 0.7 C. 9. 6/20/2023 - 0.8 C. 10. 6 /26/2023 - -0.1 C. 11. 6/29/2023 - 0.8 C. 12. 7/03/2023 - 0.5 C. 13. 7/05/2023 - 1.9 C. 14. 7/06/2023 - 1.7 C. 15. 7/10/2023 - -0.2 C. 16. 7/12/2023 - 1.9 C. 17. 7/13/2023 - 0.2 C. 18. 7/18/2023 - 1.4 C. 19. 7/19/2023 - 1.3 C. 20. 7/21/2023 - 0.3 C. 21. 7/31 /2023 - 1.5 C. 22. 8/01/2023 - 0.1 C. 23. 8/02/2023 - 0.2 C. 24. 8/07/2023 - -0.1 C. 25. 8/10/2023 - -1.8 C. 26. 8/14/2023 - 0.0 C. 27. 8/15/2023 - 1.9 C. 28. 8/16/2023 - 0.6 C. 29. 8/22/2023 - 1.8 C. 30. 8/23/2023 - 0.8 C 3. An interview with the laboratory director in the conference room on August 23, 2023 at 1:00PM, confirmed the laboratory did not document corrective actions for temperatures that were out of range.