Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0641866	05/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arizona State Public Health Laboratory	250 N 17th Ave, Phoenix, AZ	

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 performed May 1 through May 2, 2024. The facility was found to be NOT in compliance with the following CLIA conditions for specialties /subspecialties surveyed for 42 CFR: 493.1240 Pre-Analytic Systems
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, the laboratory's online "Laboratory Directory of Services", and staff interview, the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to have a system in place to ensure specimen integrity was maintained (transport conditions) per their own specifications for nine of nine patient specimens. Refer to D5311.
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 observations, review of the laboratory's online "Guide to Laboratory Services", patient test requisitions, and staff interview, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport conditions) per their own specifications for nine of nine patient specimens. Findings included: 1. On 05/01/2024 at 1:30 pm in the laboratory's specimen receiving area, observed were two brown paper bags labeled "ASL" that were delivered by a courier. The following patient specimens were received: Patient 211593; Specimen Type-Sputum; Test: AFB Testing Patient 211879; Specimen Type-Sputum; Test: AFB Testing No specimen transport temperature measurement was performed or documented for the patient specimens. The Supervisor of Specimen Receiving stamped the patient requisitions as "Received Ambient". On 05/01/2024 at 2:20 pm in the laboratory's specimen receiving area, observed were four cardboard TheraPak boxes and one brown paper bag that were delivered by the courier service. The following patient specimens were received: Patient AZ00200341; Specimen Type-Urine Isolate; Test: CRE/CRPA Patient 24472; Specimen Type-Sputum; Test: AFB Testing Patient 24543; Specimen Type-Sputum; Test: AFB Testing No specimen transport temperature measurement was performed or documented for the patient specimens. The Supervisor of Specimen Receiving stamped the patient requisitions as "Received Ambient". On 05/02/2024 at 8:50 am in the laboratory's specimen receiving area, observed were three biohazard bags and one cardboard box that were delivered by the courier service. The following patient specimens were received: Patient PIMA164686; Specimen Type-Sputum; Test: AFB Testing Patient 01DAZ240006688; Specimen Type-Sputum; Test: AFB Testing No specimen transport temperature measurement was performed or documented for the patient specimens. The Supervisor of Specimen Receiving stamped the patient requisitions as "Received Ambient". Also received were two patient stool specimens preserved Cary-Blair media vials for the following patients: Patient 0035357565; Specimen Type-Stool; Test: Shigella spp. serotyping Patient 0037940467; Specimen Type-Stool; Test: Shigella spp. Serotyping No specimen transport temperature measurement was performed or documented for the patient specimens. The Supervisor of Specimen Receiving stamped the patient requisitions as "Received Refrigerated". 2. Review of the laboratory's online "Guide to Laboratory Services" (August 2023) revealed the following transport conditions: " ...Section 2: Bacteriology Carbapenem Resistant Enterobacterales, Pseudomonas aeruginosa, Acinetobacter baumannii complex (CRE, CRPA, CRAB) ... Shipping Conditions for Isolates: Isolates sent to ASPHL should be sealed with parafilm or an equivalent and shipped at room temperature (18-25C) ... Stool Collection. Keep at room temperature (18-25C) until shipment. Transport Conditions: Ship at room temperature (18-25C). If sending an aliquot of preserved stool, please indicate this clearly on the specimen container .... Section 3: Mycobacteriology AFB Clinical: Mycobacterium tuberculosis complex, Mycobacterium spp. Acceptable Clinical Sample Types: respiratory specimens (i.e. sputum, induced sputum, bronchial washings, NP swab), bodily fluids (i.e. gastric, pleural, ascitic, CSF), tissues (i.e. biopsy, autopsy, bone), skin lesions (i. e. abscess, wound swab), urine, stool ... Conditions: Collect from symptomatic individuals only, ideally within two weeks of symptom onset. Refrigerate samples immediately after collection (2-8C) and keep refrigerated until shipment ... Transport Conditions: Ship in refrigerated (2-8C) conditions. Clinical samples must be received by ASPHL within 7 days of collection; samples received >7 days after collection will be rejected." The laboratory failed to ensure CRE/CRPA specimens were received at 18-25C, stool specimens were received at 18-25C and AFB specimens were received at 2-8C as specified in their "Guide to Laboratory Services." 3. In an interview on 05

	/01/2024 at 1:40 pm, the Supervisor of Specimen Receiving was asked how the specimen transport temperature was monitored. He stated that the temperature was not measured or documented by the specimen receiving personnel. He was asked to define ambient temperature. He stated, "anything that is not refrigerated." He further stated that if specimens were received with ice packs and they were no longer cold, he would stamp the requisition as "received ambient". He was asked if the couriers have a system to maintain and monitor specified transport temperature. He stated that he did not know if the couriers have a way to maintain transport temperature. In an interview on May 2, 2024 9:20 am, the laboratory Quality Assurance Manager and General Supervisor #9 confirmed that specimen transport temperatures were not measured or documented according to laboratory specifications. Word Key: AFB= Acid Fast Bacilli CRE= Carbapenem-resistant Enterobacterales. CRPA= Carbapenem-resistant Pseudomonas aeruginosa. Spp=species ASPHL=Arizona state public health laboratory
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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: Based on review of laboratory procedure, the Gram Stain quality control (QC) log, testing records, and confirmed in interview, the laboratory failed to follow their own procedure for the documentation of Gram Stain quality control for one of six weeks of testing. Findings included: 1. The laboratory procedure titled, "Micro 220" (Approved by the laboratory director on 05/08/2023) stated, "Quality Control positive and negative QC must be run once per week when Gram stains are preformed ..." 2. Review of the laboratory's "Gram Stain QC Log" stated "Gram stain reagents must be QC'd each week of use" and revealed gram stain QC performed on 12/01/2023, 12/07 /2023, 12/13/2023, 12/20/2023, 04/11/2024, and 04/23/2024. 3. Review of the laboratory testing records revealed that gram stains were performed on 02/27/2024. 4. In an interview on May 2, 2024, at 8:30 am, General Supervisor #9 (as listed on the submitted Centers for Medicare and Medicaid 209 form) was asked how often gram stains were performed. She stated that gram stains were performed each week of use. She was asked if there were no gram stains performed from 12/20/2023 through 04/11 /2021. After review of the laboratory's documentation, she discovered that gram stains had been performed on 02/07/2024 and confirmed the laboratory failed to document quality control.
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 the BD Bactec MGIT 960 User's Manual, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure humidity specifications were monitored for two of two instruments. Findings included: 1. During a tour of the laboratory area on 05/01/2024 at 11:20am, the BD Bactec MGIT 960 and a BD Max instrument were observed to be in use. 2. The BD Bactec MGIT 960 User's Manual stated " ...2.3 Instrument Specifications ... Environmental Requirements Operating Conditions ...Humidity 30-80% RH, non-condensing ..." The BD Max System User's Manual stated " ...3.2 Instrument Specifications ...Environmental Requirements Operating Conditions ... Humidity 20-80% RH, non-condensing ..." 3. Review of the laboratory's environmental records revealed the laboratory failed to monitor humidity levels as required by the BD Bactec MGIT 960 and BD Max manufacturers' specifications. 4. In an interview on 05/02 /2024 at 10:47am, the microbiology Technical Supervisor was asked to provide documentation of monitoring relative humidity for the MGIT 960 and BD Max instruments. No documentation was provided. This confirmed the findings. II. Based direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure manufacturers' temperature specifications were met for three of three microbiology instruments (MALDI Biotyper sirius CA System and BD Bactec MGIT 960). Findings included: 1. During a tour of the laboratory area on 05/01/2024 at 11:20am, two MALDI Biotyper sirius CA System instruments were observed to be in use Room 2233 and a BD Bactec MGIT 960 in area "VS-Bench 6". 2. The manufacturer's instruction titled, "MALDI Biotyper sirius CA System User Manual" (Ref 1890132) 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 (68F-77F) ..." The BD Bactec MGIT 960 User's Manual stated " ...2.3 Instrument Specifications ...Environmental Requirements Operating Conditions Temperature 19-30C (66.2-86 F) ..." 3. Review of the laboratory's environmental records for room 2233 revealed an acceptable temperature range of 18 - 25 C . This range exceeded the manufacturer's lower specified temperature of 20 C for sample preparation. Review of the laboratory's environmental records for "VS Room Temperature Bench 6" revealed an acceptable temperature range of 14 - 26 C . This range exceeded the manufacturer's specified low temperature of 19C 4. In an interview on 05/02/2024 at 10:47am, the microbiology Technical Supervisor, after review of the laboratory's environmental records, confirmed the findings. Word Key: BD=Becton Dickinson MGIT=Mycobacteria Growth Indicator Tube RH=Relative Humidity C=Celsius F=Fahrenheit 47107 III. Based on review of the laboratory's temperature monitoring settings, direct observation, manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure manufacturers' temperature specifications were met for 1 of 1 Biofire Filmarray Torch analyzers. Findings Included: 1. A review of the laboratory's SensoScientific temperature ranges for Bench VS-6 showed a temperature range set for 14C lower limit and 30C upper limit. 2. During a tour of the laboratory on 5/2/24 at 11:15am, one Biofire Torch analyzer was observed on Bench VS-6. 3. The manufacturer's instructions for the BIOFIRE FILMARRAY Torch (HTFA-PRT-0001-09) listed the following operations specifications: "Operating temperature 15C to 30C @ 20 to 80% relative humidity." 4. In an interview with the QA Manager in the conference room on 5/2/24 at 10:48am, it was confirmed that the temperature range set on the SensoScientific monitoring system for Bench VS-6, where the Biofire Filmarray Torch analyzer was located, had a lower limit beyond manufacturer's specifications.

	IV. Based on direct observation, manufacturer's instructions, and confirmed in interview, the laboratory failed to monitor temperature for supplies according to manufacturers' specifications for 12 of 12 Applied Biosystems MicroAmp Fast Optical 96-Well Reaction Plates, 41 of 41 Applied Biosystems Micro Amp Optical Adhesive Films, and 1 of 1 BD BBL CultureSwabs. Findings Included: 1. During a tour of the laboratory on 5/2/24 at 11:10am, the following laboratory supplies were observed in the "shared consumables area" without temperature monitoring: a. Twelve boxes of Applied Biosystems MicroAmp Fast Optical 96-Well Reaction Plates, Lot I4783Q413, expiration date 2023-11-23; manufacturer storage temperature requirements: 15-30C b. Twenty boxes of Applied Biosystems Micro Amp Optical Adhesive Films, Lot 33PCYA, expiration date 2025-04-30; manufacturer storage temperature requirements: 15-30C c. Twenty boxes of Applied Biosystems Micro Amp Optical Adhesive Films, Lot 33PPD6, expiration date 2025-06-05; manufacturer storage temperature requirements: 15-30C d. One box of Applied Biosystems Micro Amp Optical Adhesive Films, Lot 33FAET, expiration date 2023-08-02; manufacturer storage temperature requirements: 15-30C e. One box of BD BBL CultureSwab, Lot 2214224, expiration date 2027-07-31; manufacturer storage temperature requirements: 2-30C 2. In an interview within the "shared consumables area" on 5/2/24 at 11:15am, the General Supervisor #8 (as listed on the submitted Centers for Medicare and Medicaid 209 form) of microbiology confirmed that temperature monitoring was not being recorded nor documented in that area, confirming the findings. Word Key: C-Celsius @=at
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in staff interview, the laboratory failed to ensure that the correct expiration date was documented for 55 of 55 vials of US IVD BTS (Bacterial Test Standard) reagent. Findings included: 1. During a tour of the microbiology testing area on May 2, 2024, at 11:15am, fifty-five reconstituted vials of US IVD BTS were observed stored in the Thermo Scientific Freezer (Levison) labeled with a preparation date of 04/05/2024 and a revised expiration date of 10/05/2024. The revised expiration date indicated an acceptable storage time of 6 months. 2. The manufacturer's instruction titled, "MALDI Biotyper sirius CA System User Manual" (Ref 1890132) 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 (e.g. 5 ?L) into screw-cap micro tubes (0.5 mL) and close tubes tightly. Date tube. 2. Store aliquots at -18C/0F or below. Frozen, dissolved US IVD BTS can be stored for up to 5 months at -18C/0F or below ..." 3. In an interview on May 2, 2024, at 11:40 am, General Supervisor #9 confirmed that the vials were not labeled with the correct revised expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and confirmed in an interview, the laboratory failed to ensure 13 of 13 supplies were not expired and available for patient use. Findings included: 1. In direct observation, on 5/2/24 at 11: 10am, in the "shared consumables area", the following were expired: a. Twelve boxes of Applied Biosystems MicroAmp Fast Optical 96-Well Reaction Plates, Lot I4783Q413, manufacturer expiration date 2023-11-23. b. One box of Applied Biosystems Micro Amp Optical Adhesive Films, Lot 33FAET, manufacturer expiration date 2023-08-02. 2. In an interview within the "shared consumables area" on 5/2/24 at 11:15am, the General Supervisor #8 (as listed on the submitted Centers for Medicare and Medicaid 209 form) of microbiology confirmed that the supplies were expired.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory maintenance records (September 1 - December 31, 2022), and confirmed in an interview, the laboratory failed to perform and document weekly maintenance for 1 of 17 weeks (random sample) on the Cepheid GeneXpert Dx System analyzer used for testing of Carbapenemases, MTB/RIF Assay, SARS CoV-2, and Norovirus. Findings included: 1. The manufacturer's instructions for the Cepheid GeneXpert Dx System (302-0528, Rev. A), Services and Maintenance Section 9.3 listed the following maintenance requirements: "The GeneXpert instrument and computer should be powered down once per week to refresh the system. This action clears out unwanted temporary files and guards against computer memory corruption to prevent a malfunction of the system." 2. A review of the laboratory's maintenance records titled "GEN-036 Appendix A GeneXpert System Maintenance Log" from September 1, 2022 through December 31, 2022 revealed the laboratory failed to perform and document weekly maintenance from 12/12/22 - 12/16/22 on the Cepheid GeneXpert System Analyzer (Serial Number 110002465). 3. In an interview with the Technical Supervisor #2 (as listed on the submitted Centers for Medicare and Medicaid 209 form) of microbiology on 5/2/2024, within the conference room at 8:39am, it was confirmed that the laboratory should have performed weekly maintenance on the Cepheid GeneXpert System Analyzer each week, regardless of testing, thereby substantiating the deficiency finding.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the

	manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to document acceptability criteria for MGIT DST QC for pyrazinamide (PZA) susceptibility testing before reporting patient test results for 28 of 28 patients from 03/20/2024 through 04/12/2024. Findings included: 1. Review of the manufacturer's instructions titled, "BD Bactec MGIT 960 PZA kit for the Antimycobacterial Susceptibility Testing of Mycobacterium tuberculosis" stated the following: " ...User Quality Control: ...the same control organism should be run as batch QC once each week when susceptibility testing is performed. Observation of the proper results, as shown below, within 4-20 days indicates the BD BACTEC MGIT 960 PZA reagents are ready for using in testing patient isolates ..." "Proper Results" were defined as: Stains: M. tuberculosis ATCC 27294 GC: Positive BD Bactec MGIT PZA: Susceptible 2. The laboratory policy titled, "Micro 307 MGIT 960 Susceptibility" (Approved by the laboratory director 05/04/2023) stated the following: " ...Quality Control ...Testing of QC organism (MTBC ATCC 27294) must be performed weekly and completed prior to reporting results for any of the samples tested that week in the same manner as clinical samples. Additional QC testing must be performed when there are changes in lots for any of the testing components ..." The laboratory policy failed to provide quality control acceptability parameters for the PZA susceptibility testing. 3. Review of the laboratory's "MGIT Drug Susceptibility Log" from 03/20/20247 through 04/12/2024 revealed the laboratory recorded "pass or fail" as the "MGIT DST Weekly QC result". The laboratory's log failed to provide quality control acceptability parameters for PZA susceptibility testing. 4. Review of patient records from 03/20/20247 through 04/12/2024 revealed the following patients were tested: 197279, 197280, 197281, 197282, 195949, 195404, 196293, 196804, 197278, 197279, 197280, 197281, 197282, 195356, 196958, 196748, 197037, 196926, 195949, 196293 (repeat), 196804, 197521, 197522, 197204, 197821, 196923, 198188, 195356 5. During an interview on May 1,2024 at 2:00pm, the microbiology Technical Supervisor, after review of the documentation, confirmed the findings. Word Key: BD=Becton Dickinson MGIT=Mycobacteria Growth Indicator Tube M=Mycobacterium ATCC=American Type Culture Collection GC=Growth Control DST=Drug Susceptibility Testing