Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657005	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Allegheny County Health Department	3901 Penn Avenue, Pittsburgh, PA	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the technical supervisor (TS) #3, the laboratory failed to evaluate and verify the accuracy of the PT results not graded by the PT agency for 14 of 17 CAP PT testing events performed from 3/6/2024 to 3/12/2026. Findings: 1. On the day of survey, 3/12/2026 at 10:50 am, review of the laboratory's CAP PT results revealed the laboratory failed to verify the accuracy of PT results not graded by the PT agency for the following 14 of 17 CAP PT testing events performed from 3/6/2024 to 3/12/2026: a. CAP: Laboratory Preparedness: 5 of 6 events in 2024 and 2025 b. CAP: Parasitology: 3 of 3 events in 2025 c. CAP: Monkey Pox: 2 of 2 events in 2025 d. CAP: Nucleic Acid Amplification Respiratory Limited: 1 of 3 events in 2025. e. CAP: Infectious Disease Respiratory Panel: 3 of 3 testing events in 2025. 2. TS #3 confirmed the finding above on 3/12/2026 at 3:45 pm.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with the Laboratory Director, (LD), the laboratory failed to ensure that 1 of 1 laboratory procedures used for Virology and Bacteriology testing were approved, signed and dated by the current LD for 2 of 2 years from 03/06/2024 to day of survey. Findings include: 1. On the day of survey, 03/12/2026 at 09:30 am, review of the laboratory procedure manual used for Virology and bacteriology testing revealed the laboratory failed to ensure the following procedures were approved, signed, and dated by the current LD for 2 of 2 years from 03/06/2024 to 03/12/2026: - Aptima Combo 2 assay for Chamydia Trachomatis/ Niessera Gonherrra - General Bacteriology Procedure - Rapid Identification Procdure 2. The laboratory performed 17,483 bacteriology and virology tests in 2025 (CMS 116, estimated annual volume, dated 03/12/2026). 3. The LD confirmed the above findings on 03/12/2026 at 04:00 pm.
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: A. Based on lack of documentation, and interview with Technical Supervisor (TS) #2, the laboratory failed to monitor room temperature and humidity to ensure proper storage of reagents and specimens, on weekends and holidays for 208 out of 730 days from 03/006/2024 to 3/12/2026. Findings include: 1. On the day of survey, 3/12/2026 at 1:30 pm, review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperature and humidity to ensure proper storage of reagents and specimens were maintained for 208 of 730 days from 3/06 /2024 to 3/12/2026 when the laboratory was closed. 2. The following reagents were not monitored for proper storage and monitoring: Hologic Panther/Fusion system: - Aptima Combo 2 Assay Kit (Reagent box 1: 2-8 degrees Celsius; Reagent box 2: 15-30 degrees Celsius) Biofire Torch: -FilmArray GI Panel (Kit and patient sample storage 15-25 degrees Celsius) Diasorin Liaison: -XL Murex HBsAg Confirmatory (2-8 degrees Celsius) -XL Murex HCV Ab (Kit and patient sample storage 2-8 degrees Celsius) BioRad Geenius System: -HIV Confirmatory Kit (2-30 degrees Celsius) Gold Standard AIX-1000 -RPR (Kit and patient sample storage conditions 2-8 degrees Celsius) 2. The laboratory performed 17,483 total tests/examinations in 2025 (CMS 116, estimated annual volume, dated 03/02/2026). 3. TS #2 confirmed the findings above on 3/12/2026 at 2:00 pm. B. Based on observation in the laboratory, lack of documentation, and interview with technical supervisor (TS) #3, the laboratory failed to monitor daily temperatures and humidity to ensure proper operating conditions were met for 5 of 5 Olympus BX43 microscopes and 1 of 1 Olympus DP72 microscope from 3/6/2024 to 3/12/2026. 1. The manufacturer acceptable temperature and humidity range for the microscopes are as follows: - Olympus BX43 requirements: temperature 5C to 40C and humidity up to 80% Relative Humidity - Olympus DP72 requirements: temperature 10C to 35C and humidity 20% to 85%

	Relative Humidity 2. On the day of the survey, 3/12/2026 at 12:00 pm, the laboratory failed to provide temperature and relative humidity documentation to ensure proper operating conditions were met for 5 of 5 Olympus BX43 microscopes and 1 of 1 Olympus DP72 microscope from 3/6/2024 to 3/12/2026. 3. The laboratory performed 17,483 total tests/examinations in 2025 (CMS 116, estimated annual volume, dated 03 /02/2026). 4. TS #3 confirmed the findings above on 3/12/2026 at 12:45 pm.
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: Based on observation of the laboratory and interview with Technical Supervisor (TS) #3, the laboratory failed to label 1 of 1 container used to aliquot reagents with the pertinent information required for proper use from 3/6/2024 to 3/12/2026. Findings include: 1. On the day of survey, 3/12/2026 at 2:30 pm, during the laboratory tour, observation of the laboratory revealed 1 of 1 container used to aliquot reagents (saline) were not properly labeled with the following when immunology examinations were performed from 3/6/2024 to 3/12/2026: - Storage requirements - Preparation and expiration dates 2. The laboratory performed 7,010 immunology examinations in 2025 (CMS 116, estimated volume, dated 03/02/2026). 3. The LD confirmed the findings above on 03/12/2026 at 4:00 pm.
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 review of procedures, maintenance records, and interview with Technical Supervisor (TS) #2, the laboratory failed to perform and document maintenance checks as defined by the manufacturer for the Hologic Panther used for immunology examinations for 10 of 24 months from 3/6/2024 to 3/12/2026. Findings include: 1. On the day of survey, 3/12/2026 at 11:30 am, review of the laboratory's maintenance records revealed the laboratory failed to perform and document the manufacturer recommended daily, weekly and monthly maintenance checks for the Hologic Panther used for immunology examinations for 10 of 24 months (March through December 2024) from 3/6/2024 to 3/12/2026. 2. TS #2 confirmed the findings above on 3/12 /2026 at 2:00 pm.
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 lack of documentation, and interview with the laboratory director (LD), the laboratory failed to evaluate twice a year the relationship between test results using different methodologies for immunology, virology, and syphilis examinations for 2 of 2 years from 3/6/2024 to 3/12/2026. Findings include: 1. On the day of the survey, 3 /12/2026 at 1:10 pm, the laboratory failed to provide documentation for the evaluation performed twice a year to monitor and evaluate the relationship between the following methodologies used for immunology, virology, and syphllis examinations for 2 of 2 years from 3/6/2024 to 3/12/2026: - Manual vs Automated Rapid Plasma Reagin - Herpes Simplex Virus 1 and 2, Trichomonas vaginalis, Neisseria gonorrhea, Chlamydia trachomatis, Hepatitis C Virus on 2 of 2 Hologic Panthers - Gastrointestinal Panel on 2 of 2 BioMerieux Biofire Torch - Measles PCR, Monkey Pox PCR, Influenza viruses and Covid on 2 of 2 Quant Studio 2. The LD confirmed the findings above on 3/12/2026 at 3:30 pm.
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: A, Based on review of the laboratory's temperature and humidity records and interview with Technical Supervisor (TS) #2, the laboratory failed to provide documentation of the corrective actions taken for room, freezers, incubator and humidity temperatures were outside of the laboratory's established acceptable ranges for 40 of 214 days from June 2024 to December 2024. Findings include: 1. On the day of the survey, 03/12/2026 at 10:00 am, the laboratory failed to provide documentation of corrective action taken when room, freezers, incubator and humidity temperatures were outside of the laboratory's established acceptable ranges for 40 of 214 days from June to December 2024 for the following: - Incubator - 1 day (November), 9 days (December): acceptable range: 35 to 39 degree Celsius - Virology Room Temperature - 1 day (October), 5 days(November): acceptable range: 20 to 24 degree Celsius - Covid Freezer - 20 days (June): acceptable range -5 to -20 degree Celsius - Virology Room Humidity - 6 days (December): acceptable range: 20 to 50 % relative humidity - Virology Cell Cabinet - 5 days (November), 1 day (December): acceptable range: 22 to 28 degree Celsius - Virology Frezzer - 2 days (October), 4 days (Novermber) acceptable range: -16 to -25 degree Celsius 2. The laboratory performed 17,483 bacteriology and virology tests in 2025 (CMS 116, estimated annual volume, dated 03 /12/2026). 3. TS #2 confirmed the findings above on 3/12/2026 at 11:45 am. B. Based on review of the laboratory's temperature and humidity records and interview with the

	Technical Supervisor (TS) #2, the laboratory failed to provide documentation of the corrective actions taken refrigerator temperatures were outside of the laboratory's established acceptable ranges for 1 of 214 days in 2025. Findings include: 1. On the day of the survey, 03/12/2026 at 10:00 am, the laboratory failed to provide documentation of corrective action taken when refrigerator temperatures were outside of the laboratory's established acceptable ranges from June to December of 2025 for the following: - Serology Refrigerator - 1 day (October) accepptable range: 2 to 10 degree Celsius. 2. The laboratory performed 17,483 bacteriology and virology tests in 2025 (CMS 116, estimated annual volume, dated 03/12/2026). 3. TS #2 confirmed the findings above on 3/12/2026 at 11:45 am.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Technical Supervisor (TS), the laboratory failed to establish and maintain written policies for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the post analytic systems specified in 493.1291 for 2 of 2 years from 3/06 /2024 to 03/12/2026. Findings include: 1. On the day of survey, 03/12/2026 at 2:15 pm, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess, and correct problems found in the post analytic system specified in 493.1291 for 2 of 2 years from 03/06/2024 to 03/12/2026. 2. The laboratory failed to provide records for the following periodic checks performed to verify the accuracy of the Laboratory's Information System (LIS) from 03/06/2024 to 03/12/2026: - Calculated Data - Patient results transmitted between instruments and LIS - Patient Specific data. 3. The laboratory failed to provide a procedure for the use and periodic maintenance for the LIS (Clinysis). 4. The TS confirmed the findings above and stated during interview, on 3/12/2026 at 2:25 pm, "the laboratory did not have a process in place to monitor and evaluate the accuracy of information provided to clinics"
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 record review and interview with technical supervisor (TS) #3, the laboratory director (LD) failed to ensure that Quality Assurance (QA) programs were established and maintained to ensure the quality of services provided and to identify failures in quality as they occur for testing performed for 2 of 2 years from 3/6/2024 to 3/12/2026. Findings Include: 1. On the day of the survey, 3/12/2026 at 2:00 pm, review of the laboratory policy titled Quality Management System stated under the Internal Quality Assurance Monitoring section; "Quarterly, a quality assurance committee meeting will be conducted, consisting of a designated quality assurance

	facilitator, the laboratory director, and all section supervisors". 2. The laboratory failed to provide documentation that a QA committee meeting was held quarterly as defined by laboratory policy to ensure the quality of services provided and to identify failures as they occur for laboratory testing performed for 2 of 2 years from 3/6/2024 to 3/12/2026. 2. TS #3 confirmed the findings above on 3/12/2026 at 3:30 pm.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with Technical Supervisor (TS) #3, the laboratory failed to assess the competency of 2 of 3 testing personnel for microbiology testing performed in 2024 and 2025. Findings include: 1. On the day of survey, 3/12/2026 at 2:30 pm, review of competency assessment records revealed the laboratory failed to assess the competency of (CMS 209, TP #3 and #4, dated 03/12/2026) for the following microbiology testing perforrned in 2024 and 2025: -Throat Culture for Isolation and Identification of B-Hemolytic Streptococcii. 2. The laboratory did 10,473 microbiology test in 2025 (estimated volume CMS dates 03/12/2026). 3. The LD confirmed the findings above on 3/12 /2026 at 4:15 pm.