# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 42D0658606	**(X3) Date Survey Completed** 04/17/2025
Name of Provider or Supplier Sc Dph Public Health Laboratory	**Street Address, City, State** 8231 Parklane Road, Columbia, SC	
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 Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey at the SC DPH Public Health Laboratory from April 16, 2025, to April 18, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA recertification survey that concluded on April 18, 2025, at 11:15 am.
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: I. Based on laboratory personnel interview and mycobacteriology quality control record review, the laboratory failed to have a written protocol detailing the use of mycobacteriology quality control organisms used to monitor patient mycobacteriology testing. Findings included: 1. In mycobacteriology, the laboratory used quality control organisms to monitor patient mycobacteriology testing. 2. Interview with laboratory personnel on April 16, 2025 at 01:30 pm confirmed that the laboratory maintained no written protocols for the use of mycobacteriology quality control organisms that included, for example, when stock cultures of the quality control organisms are to be established from ATCC materials the laboratory purchased, how often quality control organisms are to be subcultured, etc. 3. According to laboratory records, the laboratory performed and reported approximately 2653 patient mycobacteriology cultures annually for which mycobacteriology quality control organisms were used to monitor patient testing. 27814 II. Based on review of the laboratory's manuals (clinical microbiology) and interview with Technical Supervisor #5, the laboratory failed to include quality control (QC) procedures for (Campy CVA Agar and 5 % Blood Tryptic soy agar TSA) 2 of 8 procedures reviewed as evidenced by: 1. In review of the laboratory's manual, "Camplyobacter Culture Protocol (MIC.0005)" under section "QC requirements and frequency," the laboratory did not identify which QC organisms to plate for each new lot number or shipment and their expected results for Camplyobacter media. 2. In review of the laboratory's manual, "Blood Agar (TSA 5% sheep Blood) Protocol " under section of "Quality Control," the laboratory did not identify which QC organism were to be plated for each new lot number and shipment for the media. 3. In interview with Technical Supervisor #5 on 4-16-2025 at 0949 she confirmed she was unable to find the QC organisms in the QC procedures for the Campy CVA Agar and 5 % Blood Tryptic soy agar TSA media.
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: Based on the observation of the stock room, lack of temperature records, and interview with the technical supervisor (TS) #1, the laboratory failed to document stock room conditions where Hologic Aptima specimen collection kits were stored for 11 of 20 months (September 2023 to July 2024). Findings Included: 1. Observation on April 16, 2025, at 9:15 am of the stock room revealed specimen collection kits with a manufacturer's storage requirement of, "store collection kit at room temperature (15C to 30C)": a. Thirty-nine boxes of Hologic Aptima Urine Specimen Collection Kits for Male and Female urine specimens. b. Fifteen boxes of Hologic Aptima Multitest Swab Specimen Collection Kits. c. Fifty-seven boxes of Hologic Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens. 2. The laboratory could not provide stock room temperature records for 11 out of 20 months (September 2023 to July 2024). 3. An interview with TS#1 on April 16, 2025,

	at 10:00 a.m. confirmed that the laboratory could not find the temperature logs for the stock room from September 2023 to July 2024.
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 laboratory personnel interview and QuantiFERON TB Gold-PLUS quality control record review, the laboratory failed to label QuantiFERON TB Gold-PLUS quality control materials with expiration dates. Findings included: 1. It was the practice of the laboratory to use the QuantiFERON TB Gold-PLUS test system to test patient specimens. 2. On April 16, 2025 at 10:30 am, the labels on the laboratory's unassayed QuantiFERON TB Gold-PLUS positive and negative quality control materials lot numbers FY25-2 Positive Control and FY25-2 Negative Control did not include expiration dates. 3. Laboratory personnel confirmed that these unassayed quality control materials were not labeled with expiration dates. 4. According to laboratory personnel, quality control material lot numbers FY25-2 Positive Control and FY25-2 Negative Control were used by the laboratory to monitor patient testing since 09/19/2025. As of April 16, 2025, these quality control materials were used to monitor the testing of approximately 700 patient specimens using the QuantiFERON TB Gold-PLUS test system. 38555 II. Based on observations of the media, reagents and glassware section laboratory and interviews with Technical Supervisor (TS) #1, the laboratory failed to label 10 of 10 bottles (a sample) of clinical chemicals with expiration dates that were stored in the media, reagents and glassware section laboratory. Findings Included: 1. Observation on April 15, 2025, at 2:15 pm in the media, reagents, and glassware section of the laboratory revealed the following sampling of clinical chemicals not labeled with an expiration date: a. 1 of 1 bottle of Sigma Ethylenediaminetetraacetic acid (EDTA) lot#A0434786, received: 10/7/2022, opened: 06/07/2024. b. 1 of 1 bottle of Fisher Ammonium Oxalate, lot# 055373, received: 05/25/2006, opened: 04/15/2008. c. 1 of 1 bottle of Calcium Chloride, lot#030M0145, received: 12/17/2010, opened: 01/05/2011. d. 1 of 1 bottle of Thermo Scientist Creatinine 98%, received: 10/07/2022, opened: 02/23/2024. e. 1 of 1 bottle of Sodium Thiosulfate Anhydrous, lot#136134, received: 01/10/2014, opened: 11/17/2019. f. 1 of 1 bottle of Fisher Phenolphthalein, lot#143420, received 01/27/2015, opened 01/27/2015. g. 1 of 1 bottle of Sigma Glycine, lot# SLB31578V, received: 9/15/2017, opened 09/21/2017. h. 1 of 1 bottle of Potassium Hydroxide, lot#50160, received and opened 09/13/2024. 2. Observation on April 16, 2025, at 8:30 am in the media, reagents, and glassware section of the laboratory revealed the following sampling of clinical chemicals not labeled with an expiration date: a. 1 of 1 bottle of Fisher Malachite Green Oxalate, lot# 156793, received 01/11/2016, opened 03/06/2017. b. 1 of 1 bottle of Fisher Genetics Agra, lot# 232712, received 10/20/2023, opened 01/02/2024. 3. The clinical chemicals in the media, reagents and glassware section laboratory were used to prepare medias, broths, and stains for the public health laboratory. 4. An interview with TS#1 on April 16, 2025, at 10:00 a.m. confirmed that the laboratory contacted the manufacturer regarding expiration dates, but did not document or establish expiration dates for clinical chemicals.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: I. Based on laboratory personnel interview and Gastrointestinal GI Panel Torch Biofire quality control record review, the laboratory failed to verify the stated values of commercially assayed Gastrointestinal GI Panel Torch Biofire quality control material used to monitor patient testing. Findings included: 1. It was the practice of the laboratory to use the Gastrointestinal GI Panel Torch Biofire test system to test patient specimens. 2. On April 16, 2025 at 10:15 am, commercially assayed Gastrointestinal GI Panel Torch Biofire quality control material lot number P18DEC24, expiration date 08/31/2025, was being used by the laboratory to monitor patient testing. 3. Laboratory personnel confirmed that the stated values for quality control materials lot number P18DEC24 were not verified by the laboratory prior to being used by the laboratory to monitor patient testing. 4. According to laboratory personnel, quality control material lot number P18DEC24 was used by the laboratory to monitor patient testing since 01/28/2025. As of April 16, 2025, this quality control material was used to monitor the testing of 23 patient specimens using the Gastrointestinal GI Panel Torch Biofire test system. II. Based on laboratory personnel interview and QuantiFERON TB Gold-PLUS quality control record review, the laboratory failed to establish statistical parameters for unassayed QuantiFERON TB Gold-PLUS quality control materials over time through concurrent testing of quality control materials having previously determined statistical parameters. Findings included: 1. It was the practice of the laboratory to use the QuantiFERON TB Gold-PLUS test system to test patient specimens. 2. On April 16, 2025 at 10:30 am, unassayed QuantiFERON TB Gold-PLUS quality control materials lot numbers FY25-2 Positive Control and FY25-2 Negative Control was in use by the laboratory to monitor patient testing. 3. Laboratory personnel confirmed that the statistical parameters for the unassayed quality control materials FY25-2 Positive Control and FY25-2 Negative Control had not been established over time by the laboratory through concurrent testing of quality control materials having previously determined statistical parameters. 4. According to laboratory personnel, quality control material lot numbers FY25-2 Positive Control and FY25-2 Negative Control were used by the laboratory to monitor patient testing since 09/19/2025. As of April 16, 2025, these quality control materials were used to monitor the testing of approximately 700 patient specimens using the QuantiFERON TB Gold-PLUS test system. III. Based on laboratory personnel interview and Nucleic Acid Amplification Test for MTB quality control record review, the laboratory failed to verify the stated values of commercially assayed Nucleic Acid Amplification Test for MTB quality control material used to monitor patient testing. Findings included: 1. It was the practice of the laboratory to use a Nucleic Acid Amplification Test for MTB test system to test patient specimens. 2. On April 16, 2025 at 02:00 pm, commercially assayed Nucleic Acid Amplification

	Test for MTB positive and negative quality control materials were being used by the laboratory to monitor patient testing. 3. Laboratory personnel confirmed that the stated values for these quality control materials had not been verified by the laboratory prior to being use by the laboratory to monitor patient testing. 4. According to laboratory records, the laboratory performed and reported approximately 420 patient Nucleic Acid Amplification Tests for MTB annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 for the Macro Vue, laboratory's quality control, patient testing, and interview with General Supervisor #4, the laboratory failed to document qualitative results for two positive controls for March 2025 as evidenced by: 1. In review of the BD Macro Vue RPR card manufacturer's instructions under the reading and reporting section states, "Immediately following rotation read and record as Reactive or Non-reactive." 2. In review of the laboratory's quality controls for March 2025, the ++ controls were written as a titer rather than a qualitative result. a. March 3-7 was written as 1:8 b. March 10-14 was written as 1:8 c. March 17 was written as 1:4 d. March 18 was written as 1:8 e. March 19 was written as 1:4 f. March 20th was written as 1:8 g. March 21 was written as 1:4 h. March 24-28 was written as 1:8 3. In review of the laboratory's quality control for March 2025, the + controls were written as a titer not as a qualitative result: a. March 3-7 was written as 1:2 b. March 10-14 was written as 1:2 c. March 17-21 was written as 1:2 e. March 24-28 was written as 1:2 None had the qualitative results. 4. In interview with general supervisor #4 on 4-15-2025 at 1022 she stated that they used to write and report reactive but not anymore.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, laboratory's patient testing records, and interview with General Supervisor #4, the laboratory failed to take corrective action for 2 of 10 days in April 2025 when the room temperature for RPR testing was below testing system specifications of 23-29 degrees C as evidenced by: 1. In review the laboratory procedure Syphilis RPR Assay Procedure under BD Macrovue RPR card

	test states,"Bring to 23-29 degree C prior to use." 2. In review of the laboratory's patient testing records in April 2025, the following two days the room temperature was below the testing threshold of 23-29 degrees C. a. April 1, 2025 = 22.4 degrees C. b. April 2, 2025 = 22.6 degrees C. 3. The following number of patients were tested on April 1st and April 2nd, 2025: a. April 1st = 18 patients. b.April 2nd = 7 patients. 4. In interview with General Supervisor #4 on 4-16-2025, at 1125 she stated that they didn't take corrective action when the temperatures were below the range for syphilis testing.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on the review of equipment manufacturer instructions, review of the Room Temperature and Humidity Record: Media, Reagents and Glassware Section laboratory records and an interview with Technical Supervisor (TS) #1, the laboratory failed to document corrective actions when the room temperature was not acceptable for 3 of 20 months (September 2023 to April 2025). Findings Included: 1. Under operating conditions, the Corning hot plate instructions manual stated, "ambient temperatures of 0 Celsius (C) to 30C". 2. Under meter specifications, the Thermo Scientific Orion Star A211 Benchtop and A221 and Star A321 portable pH meters reference guide states, "operating ambient temperatures of 5C to 45C". 3. On April 16, 2025, at 10:00 a.m., review of the Media, Reagents and Glassware Section Room Temperature and Humidity records revealed, the room temperature acceptable range was "15C to 30C". The back of the page was for the documentation for out-of-range corrective actions. 4. Review of Humidity Media, Reagents, and Glassware Section room temperature records revealed, the following temperatures were out of range in 2023 and 2024: a. December 21, 2023 - PM Reading: 13.4C. b. February 29, 2024 - AM Reading: 14.0C. c. September 09, 2024 - PM Reading: 56.5C. d. September 10, 2024 - PM Reading: 57.3C. e. September 11, 2024 - PM Reading: 57.8C. 5. An interview with TS#1 on April 16, 2025, at 10:45 a.m. confirmed that the laboratory did not document corrective actions for the above room temperatures that were documented out of range.