Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0662599	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Indiana State Department Of Health Laboratories	550 W 16th St, Indianapolis, IN	

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 11/19/2024 through 11/20/2024 and standard level deficiencies were cited.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the manufacturer's instructions, procedures, submitters instructions, direct observation, and interview with staff, the laboratory failed to ensure patient Aptima swabs integrity from the time of collection through receipt when transported via mail for 18 of 18 patient specimens. Findings included: 1. Review of Aptima Combo 2 manufacturer's instructions on page 7 and 8 stated, "Specimen Transport and Storage Before Testing ...Urogenital Swab Specimens a. After collection, transport and store the swab in the swab specimen transport tube at 2C to 30C until tested. Specimens must be assayed with the AC2 assay within 60 days of collection. If longer storage is needed, freeze urogenital specimens in the swab specimen transport tube within 7 days of collection at -20C to -70C to allow testing up to 12 months after collection." For "Extragenital Swab Specimens (throat and rectal) a. After collection, transport and store the swab in the swab specimen transport tube between 4C and 30C, or -20C and -70C until tested. Specimens must be assayed with the AC2 assay within 60 days of collection." For "Urine Specimens a. Maintain urine specimen at 2C to 30C after collection and transfer to the Aptima urine specimen transport tube within 24 hours of collection. Transport to the lab in the primary collection container or the transport tube at 2C to 30C. Store at 2C to 30C and test the processed urine specimens with the AC2 assay within 30 days of collection. b. If longer storage is needed, freeze urine

	specimens in the Aptima urine specimen transport tube within 7 days of collection at -20C to -70C to allow testing up to 12 months after collection." 2. Review of the laboratory's Aptima Combo 2 Assay procedure (IDOH-MOL-62) stated on page 7, "Specimen Handling Requirements A. Swab and urine specimens must be transported to the laboratory at 2-30C in Aptima urine or unisex swab collection kits." 3. Review of the laboratory's instructions for submitters stated, "Urine and swab specimen must be kept at 2-30C ..." and for Shipping Instructions to place the specimen in a cannister and then into an outer shipping cannister and mail to the laboratory. The "Specimen Transport Guide" for CT/GC for temperature conditions stated, "Ambient or Refrigerated, Category B." Ambient and Refrigerated temperatures were not defined. 4. During a tour of Central Accessioning (first floor) on 11/20/2024 at 10:07 am, a drop-off from United Parcel Service (UPS) was observed (9 packages). On the "CT /GC & Serology Log" was documented 4 packages from UPS at "Room Temperature" with a log-in time of 10:14 am and 3 packages from UPS at "Room Temperature" with a log-in time of 10:15 am. Room temperature had not been defined. On 11/20 /2024 at 10:34 am, a serology testing person was observed picking up the CT/GC UPS packages and taking them to the second floor (serology department) for processing. 5. During an observation of the Serology department on 11/20/2024 at 10:34 am, the testing person opened UPS packages, and they included cannisters of Aptima swabs (total of 18) within biohazard bags and manifests. The laboratory did not have a system in place to ensure Aptima swab specimens maintained the required temperature of 2C to 30C (urogenital and urine) and 4C and 30C (for extragenital swabs) during transport. The laboratory did not ensure Aptima swab specimen integrity.
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: I. Based on observation, review of laboratory procedures, review of the laboratory online test menu and interview with staff, the laboratory failed to provide transport temperature and timeframe requirements to clients for specimens for Tuberculosis /Mycobacteriology Specimen Testing. Findings included: 1. During observation of the Accessioning area on 11/20/2024 at approximately 10am, the laboratory received a United Parcel Service (UPS) shipment of several specimens for Tuberculosis testing in a plastic UPS bag. The temperature of the specimens was not taken in the accessioning area. The accessioning staff placed the plastic bag in a red bin in a temperature monitored refrigerator (serial number 174661) located in the accessioning area. At approximately 10:20am, staff from the Tuberculosis (TB) laboratory removed the plastic bag from the refrigerator in the accessioning area and carried the bag to the TB laboratory, Room 225A. The bag was opened, and a screw top can containing specimens was removed. 2. Review of the laboratory's procedure named "ISDH-TB-05 (Mycobacteriology Culture)" found transport conditions for specimens were not addressed. 3. Review of the laboratory's online test menu (https://www.in.gov/health /laboratories/testing/available-tests/) revealed the following for test type "Tuberculosis

	/Mycobacteriology Specimen Testing": under "Procedural Notes" ... If a delay in shipping is anticipated, be sure to keep the specimens refrigerated at 4 C prior to shipping to minimize the growth of contaminants."; under "Shipping Instructions" no information was provided to the client regarding the temperature or timeframe for shipping specimens to the laboratory. 4. During interview on 11/20/2024 at approximately 9:10am, the Quality Assurance Director confirmed specimen transport conditions were not defined in the online test menu. 43232 II. Based on review of the laboratory's procedure, direct observation, and a final test report, the laboratory failed to follow their own written procedure for storing one of one specimens for human immunodeficiency virus (HIV) testing in a -20C or colder freezer. Findings included: 1. Review of the laboratory's procedure for Geenius HIV 1/2 Assay (IDOH-SER-32) on page 7 stated, "8.0 Specimen Handling Requirements For long-term storage, the serum should be frozen (at -20C or colder)." 2. During a tour of the laboratory on 11 /20/2024 at 1:15 pm, patient #C24060133 specimen was observed stored in a freezer with a temperature reading of -18C. The specimen was positive for HIV Ag/Ab (antigen/antibody) and awaiting confirmatory testing with the Geenius. 3. Review of patient #C24060133 final test report included a report date of 11/21/2024 for HIV Ag /Ab and Geenius HIV 1/2 tests. The laboratory failed to store HIV specimens awaiting additional testing in a -20C or colder freezer.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's client services manual and interview with technical supervisor - 8 (TS-8), the laboratory failed to define storage and transport temperatures in their client services manual for 7 of 7 tests (random sampling). Findings included: 1. Review of the laboratory's online instructions for their submitters (client services manual) included the following (random sampling): Arbovirus Testing - Specimen Requirements - "2. Specimens may be stored at refrigerated or frozen temperature." Hepatitis B - Specimen Requirements - "2. Specimens may be stored at refrigerated, frozen or room temperature. 3. Specimens must arrive at the lab within 24 hours of collection if stored at room temperature." Hepatitis C - Specimen Requirements - "2. Specimens may be stored at refrigerated, frozen or room temperature." HIV Testing - Specimen Requirements - "2. Specimens may be stored at refrigerated, frozen or room temperature." Syphilis Testing - Specimen Requirements - "2. Specimens may be stored at refrigerated, frozen or room temperature." The laboratory had not defined "refrigerated," "frozen," or "room" temperatures to ensure optimum integrity of specimens. 2. Review of the laboratory's "Indiana Courier System: Specimen Transport Guide" for their submitters included the following (random sampling): Blood Lead - Temperature Conditions - for whole blood "Ambient, Category B" and for whole blood filter paper "Ambient." Arbovirus - Temperature Conditions - "Refrigerated, Category B**." Chlamydia/Gonorrhea - Temperature Conditions - "Ambient or Refrigerated, Category B." Hepatitis B - Temperature Conditions - "Refrigerated, Category B**." Hepatitis C (Serology) - Temperature Conditions - "Ambient or Refrigerated, Category B**." HIV - Temperature Conditions - "Ambient, Category B**." Syphilis - Temperature Conditions - "Ambient, Category B**." The laboratory had not defined "refrigerated,"

	or "ambient" temperatures to ensure optimum integrity of specimens. 3. During an interview on 11/20/2024 at 3:44 pm, TS- 8 stated their courier system has continuous temperature monitoring and room temperature was defined as 15C to 30C. TS-8 stated this is the temperature everyone had agreed on. A source for this temperature was not provided. The laboratory had not defined "refrigerated," "frozen," "ambient" or "room" temperatures in their written instructions for specimen handling.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions, and the Hologic instrument report, the laboratory failed to follow manufacturer's instructions for ensuring 18 of 18 observed Aptima patient specimen containers did not contact one another. Findings included: 1. During a tour of the serology department on 11/20/2024 at 10:34 am, the following was observed being received: UPS (United Parcel Service) packages included cannisters - five Aptima patient specimen containers in one biohazard bag, four Aptima patient specimen containers in one biohazard bag, three Aptima patient specimen containers in one biohazard bag, three Aptima patient specimen containers in one biohazard bag, three Aptima patient specimen containers in one biohazard bag. Specimens were touching one another in the biohazard bags. 2. Review of Hologic Aptima Combo 2 Assay manufacturer's instructions stated (page 5), "O. Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high level of organisms. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers." 3. The following was a sampling of the observed Aptima patient specimens touching one another during transport and analyzed on the Hologic Panther for Chlamydia trachomatis and Neisseria gonorrhea on 11/20/2024: C24060514 (collected 11/15/24) C24060515 (collected 11/15/24) C24060516 (collected 11/15/24) C24060517 (collected 11/18/24) C24060610 (collected 11/19/24) C24060611 (collected 11/19/24) C24060612 (collected 11/19/24) C24060613 (collected 11/18/24) C24060614 (collected 11/18/24) The laboratory failed to ensure Aptima patient specimens did not touch one another during transportation. II. Based on review of manufacturer's instructions, direct observation, written procedures, and interview with staff and the manufacturer, the laboratory failed to ensure the manufacturer's dropping bottle and dispensing needle were used for rapid plasma regain (RPR) testing for 22 of 22 patient specimens. Findings included: 1. Review of Sure-Vue RPR manufacturer's instructions stated, "1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed." The material provided by Sure-Vue included: "3 ml Dropping bottle" and "20-ga Dispensing Needle (60 drops /ml)" used to dispense the Carbon Antigen. 2. During a tour of the laboratory on 11/20 /2024 at 12:46 pm, a bottle of Sure-Vue RPR Carbon Ag (Lot 4C2OR9, expiration date 12-31-25) was observed stored on the on the counter with the rest of the RPR testing supplies. An RPR Carbon Antigen dropping bottle, and a dispensing needle was not observed with the RPR supplies. Twenty-two patient specimens were observed in a rack on the counter that had been RPR tested. 3. During an interview on 11/20/2024 at 3:00 pm, the general supervisor for serology was asked whether the

	dropping bottle and dispensing needle were used for RPR carbon antigen. She stated no, a pipette was used. 4. Review of the laboratory's written procedure for RPR testing (IDOH-SER-7) stated on pages 9,10, and 12, "Attach the syringe to the repeating pipettor. Draw up a sufficient volume of carbon antigen into the syringe. Prime the pipettor a few times by dispensing several drops of carbon antigen back into the vial. Dispense one drop (17ul) of carbon antigen into each well on the card." Review of Sure-Vue RPR manufacturer's instructions stated, "Attach the needle to the dropping bottle. Mix the CARBON ANTIGEN suspension well. Squeeze the dropping bottle and draw a sufficient volume of the antigen suspension into the bottle. Dispense several drops into the dropping bottle cap to sure the needle passage is clear ... Dispense one free-falling drop of antigen suspension onto each sample while holding the bottle in a vertical position ..." 5. During a telephone interview on 11/21/2024 at 2: 06 pm with the Arlington Scientific Executive Vice President of Operations and Compliance, he was asked about using a repeating pipettor for dispensing carbon antigen versus the dropping bottle and dispensing needle that comes with the RPR kit. He stated the dropping bottle, and dispensing needle must be used to dispense carbon antigen and not a repeating pipettor.
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 temperature logs and review of the instrument operator's manual, the laboratory failed to ensure room temperature was within manufacturer's specifications for the Bruker MALDI Biotyper sample preparation area. Findings included: 1. One Bruker MALDI Biotyper CA analyzer and one MALDI Bruker Biotyper CA sirius analyzer were observed in the sample preparation area during a tour of room 225A at approximately 1:15pm on 11/19/2024. 2. Review of the room temperature logs for room 225A indicated an acceptable room temperature of 17C - 27C. 3. The operator manual for the Bruker MALDI Biotyper CA sirius analyzer stated the following: "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/+68F to +25C/+77F ...For best results, preparation of all solutions, Standard Solvent, and the entire sample preparation process including drying steps must be performed under controlled room temperature." II. Based on observation, review of temperature logs, review of manufacturer's instructions and interview with staff, the laboratory failed to ensure the humidly level was within manufacturer's specifications for the BD BACTEC MGIT 960 analyzer. Findings included: 1. One BD BACTEC MGIT 960 analyzer was observed during a tour of room 225A at approximately 1:06pm on 11/19 /2024. 2. Review of the room temperature logs for room 225A indicated documentation of daily temperature, but no documentation of daily humidity. 3. The operator manual for the BD BACTEC MGIT 950 system states the following: "2.3 Instrument Specification ... Environmental Requirements ...MGIT 960 ...Operating

	Conditions ...Humidity 30% - 80% RH, non-condensing" 4, During interview on 11/19 /2024 at approximately 1:06pm, the Technical Supervisor for the Mycobacteriology section confirmed the above findings. III. Based on observation of media/reagents stored in refrigerator and review of the laboratory's temperature monitoring system (ViewPoint) the laboratory failed to ensure manufacturer temperature requirements for storage of media/reagents. 1. During tour of Mycobacteriology Room 225 on 11/19 /2024 at approximately 2pm, the following items were observed stored: a. Refrigerator with serial number 11200 contained two boxes of BD BACTEC MGIT 960 Sire Kits, Lot #3324473, Expiration 2025-02-22, store 2C - 8C; and nine boxes of BD BBL Lowenstein-Jensen Medium Gruff, Lot #57802722, Expiration 2025-08-22, store at 2C - 8C. b. Refrigerator with serial number 09716 contained three boxes of QuantiFERON TB-Gold Plus kits, Lot #57802722, Expiration 2027-01-03, store at 2C - 8C. c. Review of ViewPoint temperature logs for refrigerator serial number 11200 for 11/19/2024 found the temperature alerts were set for a lower limit of -3C and an upper limit of 10C. Review of ViewPoint temperature logs for refrigerator serial number 09716 for 11/19/2023 thru 11/19/2024 found the temperature alerts were set for a lower limit of -3C and an upper limit of 10C. IV. Based on direct observation and review of temperature logs, the laboratory failed to ensure temperatures in the laboratory met manufacturer temperature requirements. 1. During tour of Virology Room 235 on 11/20/2024 at approximately 2pm, the following was observed stored on the counters: a. One box of Biofire Respiratory Panel 2.1 kit, Lot #0275724, Expiration 2025-08-04, store at 15C - 25C. b. Two boxes of QIAamp Viral RNA Mini Kit, Lot #175042786, Expiration 2025-01-05, store at 15C - 25C. c. One box of QIAamp DSP DNA Blood Mini Kit, Lot #178014958, Expiration 2025-05-19, store at 15C - 25C. 2. Review of the" Equipment Temperature Log" for Virology Room 235 for the months of July, August and September of 2024 revealed an acceptable temperature range of "15 to 30C".
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 and interview with testing personnel, the laboratory failed to label 3 of 3 secondary containers of bovine blood with identity, storage requirements and expiration dates. Findings included: 1. During a tour of the blood lead department on 11/19/2024 at 12:00 pm, the following three plastic conical tubes with blue tops were observed stored under a hood labeled with: "Blood BLK", "BLK", and "Blood Pb Blk" The tubes were used as secondary containers for bovine blood and not labeled with identity, storage requirements and expiration dates. The blood was used for blood lead calibration curves. 2. During an interview on 11/20/2024 at 1: 30 pm, testing persons 6 and 7 (as listed on CMS-209 form) confirmed the above secondary tubes were bovine blood and not labeled with the requirements.