Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0691828	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Department Of Public Health -Chicago	2121 W Taylor St, Chicago, IL	

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	An announced CLIA recertification survey was conducted at the ILLINOIS DEPARTMENT OF PUBLIC HEALTH - CHICAGO from January 14, 2025 to January 16, 2025 by federal surveyors from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be compliance with condition-level CLIA requirements but not standard-level CLIA requirements. The following standard-level deficiencies were found during the CLIA recertification survey completed on January 16, 2025.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on the review of the clinical quality manual standard operating procedures (SOP), and interview with the Senior Public Service Administrator (PSA) the laboratory failed to follow their competency assessment procedure to assess the competency for 4 out of 13 general supervisors (GS) and 4 out of 10 technical supervisors (TS) in 2023 and 2024. Findings Included: 1. The clinical quality manual, 2.6.2 Competency assessment of non-testing personnel, 2.6.2.2 stated, "technical supervisor: Personnel Competency Assessment and documentation of the performance of individuals for clinical technical supervisor is a CLIA requirement....Therefore, assessment must be performed at least annually". 2. The clinical quality manual, 2.6.2 Competency assessment of non-testing personnel, 2.6.2.3 stated, "general supervisor: Personnel Competency assessment and documentation of the performance of individuals for clinical technical supervisor is a CLIA requirement....Therefore, assessment must be performed at least annually". 3. On January 15, 2025, 10:00 am, the PSA could not provide the following competency assessments for 4 out of 13 GS

	and 4 out of 10 TS in 2023 and 2024: a. Laboratory personnel listed as TS08 / GS08 was not assessed for TS/GS competency in 2023 and 2024. b. Laboratory personnel listed as TS10 / GS13 was not assessed for TS/GS competency in 2023. c. Laboratory personnel listed as TS06 / GS06 was not assessed for TS/GS competency in 2023. d. Laboratory personnel listed as TS09 / GS12 was not assessed for TS/GS competency in 2023. 4. Interview with the PSA on January 15, 2024, at 11:00 am confirmed the findings above. II. Based on the review of clinical quality manual standard operating procedures (SOP), and interview with the Senior Public Service Administrator (PSA), the laboratory failed to establish a competency assessment procedure and assess the competency for one of one clinical consultant (CC) from 2023 to 2024. Findings Include: 1. Review of the clinical quality manual on January 14, 2024, at 1:00 pm revealed the standard operating procedure did not include the assessment for clinical consultants. 2. The laboratory personnel report (CLIA) Form CMS-209 signed by the laboratory director on January 13, 2025, listed one of one CC. 3. Interview with the PSA on January 14, 2024, at 1:30 pm confirmed the SOP did not include an assessment for CC and the CC was not assessed for competency in 2023 and 2024.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on observation of received specimen, review of laboratory standard operating procedures (SOP), and interviews with technical supervisor (TS) #03 and TS #09, the laboratory failed to document specimen acceptability temperatures for newborn screening (NBS) and Molecular Virology specimens received from December 10, 2024, to January 16, 2025. Findings Included: 1. The Clinical Quality Manual SOP on page 31, 6.8 Specimen Submission. Handling and Referral, 6.8.2.3. stated, "Laboratory must document the temperature of content of specimen packages using an infrared thermometer. Temperatures of the specimen and initials of individuals who took the temperature are documented on the submission form or in a LIMS, if available". 2. The Newborn Screen Operation SOP page 5, 3.2.2.2. Acceptable Temperature Ranges stated, "The acceptable temperature range for newborn screening specimens/shipments is 2C - 30C". 3. The Detection of Influenza A, Influenza B, and SARS-CoV-2 by Multiplex real-time RT-PCR (CDC Influenza SAR-CoV-2 Multiplex rRT-PCR) standard operating procedure, 3. Requirements for Specimen Collection and Handling, 3.1.1.5.2 stated, "Refrigerate specimen at 2C - 8C and ship overnight on ice packs" 3.6.4.1. "Specimens received frozen (on dry ice), stated, "specimens can be tested if they are received beyond 72 hours of collection provided, they have been frozen an maintained at -70C and received on dry ice". 4. Observation of NBS specimens received on January 15, 2025, at 11:50 am revealed, specimens received were entered into the LIM system as either 2C - 30C or outside 2C - 30C. 5. Observation of the Molecular Virology specimens received on January 16, 2025, at 12: 15 pm, revealed frozen specimens received were documented as "Frozen". 6. From December 10, 2024 to January 16, 2025, 9,475 NBS specimens were received by the laboratory. 7. From December 10, 2024 to January 16, 2025 the following frozen

	molecular virology specimens were received by the laboratory: a. Influenza - 8 out of 36 specimens. b. Influenza / SARS - 120 of 12,070 specimens. 8. An interview with TS #9 on January 15, 2025, at 12:30 pm confirmed NBS specimens received were not documented as the temperature received. 9. An interview with TS #3 on January 16, 2025, at 12:30 pm confirmed frozen virology specimens were not documented as the temperature received. 46043 II. Based on review of manufacturer's instructions, laboratory policies, laboratory's online specimen collection and submission instructions, and confirmed in staff interview, three of three laboratory policies failed to provide a system to ensure specimen integrity (storage and transport) was maintained. Findings included: 1. The manufacturer's instructions titled "Xpert MTB /RIF" (301-1404, Rev. G. July 2020) stated, " ...8.2 Storage and Transport Sputum sediment: Store resuspended sediments at 2-8C for up to seven days. Raw sputum: Transport and store specimens at 2-8C before processing whenever possible. If necessary, sputum specimens can be stored at a maximum of 35C for up to three days and then at 2-8C for an additional seven days ..." 2. The laboratory policy titled "Mycobacteriology General Protocols for Specimen Receipt, Processing, and Culture" (SOP Number CCY026-18-1224) stated, " ...3.1.9 Specimens should reach the laboratory within 5 days of collection ..." The policy failed to provide specific temperature requirements for storage and transport. 3. The laboratory policy titled "Detection of rifampin-resistant Mycobacterium tuberculosis complex (MTBC) by the Cepheid GeneXpert Assay (SOP CCY030-09-1224) stated, " ...3.2 sputum specimens must be collected in a sterile plastic container and stored at 2-8C until transported. If necessary, specimens can be stored at a maximum of 15-25C for up to three days and then at 2-8C for an additional seven days ..." This policy failed to specify different storage and temperature requirements for sputum sediment and raw sputum. 4. The laboratory's online specimen collection and submission instructions titled "Laboratory Manual of Services" stated " ...Instructions for Specimens sent for Diagnosis ... 18. Transport specimens to the laboratory as soon as possible; specimens should reach the laboratory within 5 days of collection ...5. If the specimen(s) cannot be shipped immediately: 1. Store at 4 to 8C 2. Transport specimens to the laboratory as soon as possible a. Specimens must reach the laboratory within 5 days of collection ..." The instructions for specimen storage differed from laboratory policy and manufacturer's instructions. The instructions failed to provide temperature requirements for specimen transport. 5. In an interview on 01/15/2025 at 11:30 am in Room 131G, Testing Person #51 (as listed on the CMS-209 form) was asked what the acceptable criteria for specimen submission was. She stated the specimen must be within 2-25 C and not be over 10 days old. This did not correspond to laboratory policies or online instructions. In the interview, the Mycobacteriology Technical Supervisor confirmed the discrepancies in the laboratory policies and the online instructions to clients. Word Key: SOP=Standard Operating Procedure MTB= Mycobacterium tuberculosis RIF=Rifampin
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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: Based on review of manufacturers' instructions, laboratory procedure and confirmed

	in staff interview, the laboratory failed to follow manufacturer's instructions for tuberculosis (TB) Auramine-Rhodamine acid fast staining procedure for two of two years. Findings included: 1. The manufacturers' instructions for TB Auramine-Rhodamine (IFU 40090, Revised November 11, 2004), TB Decolorizer (IFU 40107, Revised November 11, 2004), and TB Potassium Permanganate (IFU 40092, Revised November 11, 2004) all stated: " ...Procedure ...2. Flood the smear with TB Auramine-Rhodamine for 15 minutes at room temperature 3. Rinse with demineralized water and drain 4. Decolorize with TB Decolorizer for 2-3 minutes 5. Rinse with demineralized water and drain 6. Flood smear with TB Potassium Permanganate counterstain for no longer than 2-4 minutes 7. Rinse with demineralized water and allow to air dry ..." 2. The laboratory procedure titled "Mycobacteriology General Protocols for Specimen Receipt, Processing, and Culture" (SOP Number CCY026-18-1224) stated, " ...6.2.6.2.3 Flood smears with Auramine-Rhodamine reagent for 15 minutes 6.2.6.2.4 Rinse off stain with tap water and drain 6.2.6.2.5 Decolorize for 2-3 minutes 6.2.6.2.6 Rinse smear with tap water and drain 6.2.6.2.7 Flood smears with potassium permanganate and incubate for 2-4 minutes 6.2.6.2.8 Rinse smears, drain, and air dry ..." The laboratory failed to use demineralized water, as specified in the manufacturer's instructions, to rinse smears. 3. In an interview on January 15, 2024, at 12:30 pm, the Mycobacteriology Technical Supervisor confirmed the laboratory used tap water to rinse smears.
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: I. Based on observation of the laboratory in room #364A, review of the appliedbiosystems Taqman RNase P Control Reagents Kit safety data sheets (SDS), review of a sampling of freezer #88588 temperature records, and interview with the technical supervisor (TS) #5, the laboratory failed to follow and defined criteria for the storage of 1 of 1 appliedbiosystems Taqman RNase P Control Reagents Kit. Findings Included: 1. On January 16, 2025 at 2:00 pm, tour and observation of the laboratory in room #364A revealed, 1 of 1 box of appliedbiosystems Taqman RNase P Control Reagents Kit was stored in freezer #88588. 2. On January 16, 2025 at 2:20 pm, review of the appliedbiosystems Taqman RNase P Control Reagents Kit SDS revealed, the manufacturers stated, "Contents and storage: -25C to -15C". 3. On January 16, 2025 at 2:25 pm, review of freezer #88588 temperature records revealed the laboratory reference ranges were defined as, less than or equal to -16C. 4. A review of a sampling of freezer temperature records revealed the following temperature were outside the manufacturers established reference ranges (-25C to -15 C) in 2024: a. September 2024 - 8 out 21 working days. b. October 2024 - 16 out of 23 working days. c. November 2024 - 12 out of 21 working days. d. December 2024 - 14 out of 22 working days. 4. Interview with TS #5 on January 16, 2025 at 2:50 pm confirmed the above findings. 38798 II. Based on review of the Standard Operation

Procedure for Determination of Blood Lead Level (BLL) by Thermofisher iCAP RQ /Q ICP-MS, the BioRad Lyphocheck Whole Blood Metals Control Levels 1, 2, and 3 package insert, the room temperature logs, and staff interview, the laboratory failed to ensure the room temperature ranges were within the quality control manufacturer's specifications before use of the quality control material on 72 days out of 498 days of testing. Findings included: 1. A Standard Operation Procedure for Determination of Blood Lead Level (BLL) by Thermofisher ICAP RQ/Q ICP-MS stated, "8.4.1.5 Follow instructions in package insert." 2. A BioRad Lyphocheck Whole Blood Metals Control Levels 1, 2, and 3 package insert stated, "If the product has been stored refrigerated, allow it to reach room temperature (18 to 25C) before use." 3. A review of the Room Temperature/Relative Humidity Log for room 266/267 revealed an acceptable temperature range of 15 to 30C. 4. A review of the Room Temperature /Relative Humidity Log for room 266/267 revealed the room temperature for 72 days out of 498 test days were not within the quality control manufacturer's specified room temperature range. Test dates and room temperatures out of range are as follows: 01 /19/2023 26.7C 01/20/2023 25.9C 01/24/2023 25.5C 01/25/2023 26.1C 01/26/2023 26.7C 02/02/2023 25.3C 02/07/2023 25.9C 02/08/2023 26.3C 02/09/2023 26.1C 02/10 /2023 26.1C 02/14/2023 26.1C 02/15/2023 26.3C 02/16/2023 26.2C 02/17/2023 26.3 C 02/21/2023 26.6C 02/22/2023 26.6C 02/23/2023 26.6C 02/24/2023 26.4C 02/27 /2023 26.3C 02/28/2023 26.4C 03/01/2023 26.7C 03/02/2023 26.6C 03/03/2023 26.8 C 03/06/2023 26.9C 03/07/2023 26.1C 03/08/2023 26.6C 03/09/2023 26.7C 03/10 /2023 26.3C 03/13/2023 25.9C 03/15/2023 26.3C 03/16/2023 25.6C 03/17/2023 27.4 C 03/20/2023 26.6C 03/21/2023 25.7C 03/22/2023 26.6C 03/23/2023 26.4C 03/24 /2023 26.6C 03/27/2023 26.6C 03/28/2023 26.3C 03/29/2023 27.1C 03/30/2023 27.3 C 03/31/2023 26.8C 04/03/2023 27.4C 04/04/2023 26.8C 04/05/2023 30.5C 04/06 /2023 26.8C 04/07/2023 26.6C 04/11/2023 28.2C 04/12/2023 27.3C 04/13/2023 28.4 C 04/14/2023 28.2C 04/17/2023 25.7C 04/25/2023 26.1C 04/26/2023 27.1C 05/30 /2023 26.7C 06/01/2023 25.3C 06/23/2023 25.3C 06/28/2023 26.9C 06/29/2023 26.9 C 06/30/2023 26.8C 07/03/2023 26.3C 07/05/2023 26.6C 07/06/2023 26.3C 07/13 /2023 25.1C 07/14/2023 25.7C 07/17/2023 25.1C 07/19/2023 25.9C 07/24/2023 25.6 C 07/25/2023 25.9C 10/26/2023 25.8C 10/27/2023 25.4C 03/14/2024 26.0C 5. An interview with the Technical Supervisor for Blood Lead Level testing on January 15, 2025 at 11:39 AM confirmed the room temperature range set by the laboratory was 15 to 30C and the temperature logs showed 72 out of 498 days that the room temperature for room 266/267 exceeded 25C. 46043 III. Based on direct observation, review of manufacturer's instructions, review of laboratory environmental records (2024), and confirmed in staff interview, the laboratory failed to ensure operating temperature and humidity ranges were within manufacturer's specifications for 12 of 12 months (temperature) and 10 of 10 months (humidity). Findings included: 1. During a tour of the mycobacteriology testing area on January 15, 2024, at 11:30 am, the following three Bactec MGIT automated mycobacterial detection system instruments were observed in Room 131F: MGIT 320, Serial Number MT0402 MGIT 960 #1, Serial Number MG0323 MGIT 960 #2, Serial Number MG0606 2. The manufacturer's instructions for the Bactec MGIT automated mycobacterial detection system (MA-0117-A) stated " ...Operating Conditions Temperature 19C - 30C ...Humidity 30% -80% RH, non-condensing ..." 3. The laboratory's 2024 environmental records for Room 131F stated an acceptable temperature range of 17C - 29C. The laboratory's lower limit (17C) was below the lower limit specified by the manufacturer (19C). Further review of the laboratory's 2024 environmental records for Room 131F revealed the laboratory stated an acceptable relative humidity range of 20%-75% from March 2024 through December 2024. The laboratory's lower limit (20%) was below the lower limit specified by the manufacturer (30%). 4. In an interview on January 15, 2024, at 12:00 pm, the Mycobacteriology Technical Supervisor confirmed the

	findings. IV. Based on direct observation, review of manufacturer's instructions, review of laboratory environmental records (2024), and confirmed in staff interview, the laboratory failed to ensure Auramine-Rhodamine staining reagents were stored according to manufacturer's specifications for 12 of 12 months. Findings included: 1. During a tour of the mycobacteriology testing area on January 15, 2024, at 11:30 am, the following Auramine-Rhodamine staining reagents were observed: Room 131G /Processing One bottle TB Auramine-Rhodamine, Lot number 144492, Expiration date 08/02/2025 One bottle TB Decolorizer, Lot number 144865, Expiration date 01 /24/2026 One bottle TB Potassium Permanganate, Lot number 145703, Expiration date 07/30/2025 Room 136B Two boxes of 5 bottles each, TB Decolorizer, Lot number 144865, Expiration date 01/24/2026 One box of 5 bottles, TB Potassium Permanganate, Lot number 145703, Expiration date 07/30/2025 2. The manufacturers' instructions for TB Auramine-Rhodamine (IFU 40090, Revised November 11, 2004), TB Decolorizer (IFU 40107, Revised November 11, 2004), and TB Potassium Permanganate (IFU 40092, Revised November 11, 2004) all stated, " ...Storage ... Store product in its original container at 20C - 25C until used ..." 3. Review of the laboratory's 2024 environmental records for Room 131G and 136B revealed an acceptable room temperature range of 17C - 29C. This room temperature range exceeded the upper and lower limits of the manufacturer's instructions for the staining reagents. Further review of the environmental records for Room 136B for April - May 2024 revealed the following 21 of 40 days where the temperature was outside of manufacturer's acceptable range: April 16: 19C April 17: 19C April 18: 19C April 29: 19C April 30: 19C May 1: 18C May 2: 19C May 6: 18C May 10: 19C May 13: 19C May 14: 18C May 15: 19C May 17: 18C May 20: 18C May 21: 19C May 22: 18C May 23: 17C May 24: 18C May 29: 19C May 30: 18C May 31: 19C 4. In an interview on January 15, 2024, at 12:00 pm, the Mycobacteriology Technical Supervisor confirmed the findings. Word Key: RH=Relative humidity
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: 46043 Based on direct observation, review of manufacturer's instructions, and confirmed in staff interview, the laboratory failed to ensure that the correct expiration dates were documented for four of four vials of US IVD BTS (Bacterial Test Standard) reagent. Findings included: 1. During a tour of the microbiology testing area on January 16, 2024, at 10:30 am, a box of four reconstituted, aliquoted vials of US IVD BTS (Lot number 603042F004) were observed stored in the freezer in Room 473 labeled with a preparation date of 12/27/2024 and an expiration date of 02/28 /2026. 2. The manufacturer's instruction titled, "Instructions for Use Bruker Bacterial Test Standard" (Revision 1 July 2012) stated, " ...Frozen, dissolved US IVD BTS can be stored for up to 5 months at -18C/0F or below ..." The laboratory failed to label dissolved and aliquoted vials with a revised expiration date of 5 months. 3. In an interview on January 16,2024, at 10:35 am, the Microbiology Technical Supervisor confirmed that the vials were not labeled with the correct revised expiration date.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observations of the new born screening (NBS) Molecular laboratory and interview with the technical supervisor (TS) #5, the laboratory failed to discard 18 out to 18 bottles of expired Decon SaniHol 70 Ethanol Solution in 2024. Findings Included: 1. Observations of the NBS Molecular laboratory on January 16, 2025 at 2: 15 pm, revealed one of 18 expired bottles of Decon SaniHol 70 Ethanol Solution in use and 17 of 18 expired bottles stored on a shelf in the laboratory. 2. 18 out to 18 Decon SaniHol 70 Ethanol Solution bottles, Lot#A03042207R, expired March 2024. 3. Interview with the TS #5 on January 16, 2025 at 2:20 confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the clinical quality manual standard operating procedures (SOP), lack of performance specifications records and interview with technical supervisor (TS) #3, the laboratory failed to verify the performance specifications for 1 of 2 Thermofisher QuantStudio 7500 DX instruments used to analyze Measles and Mumps viruses before use in 2024. Findings Included: 1. The clinical quality manual SOP, 7.5 Established and Verification of Performance Specifications states, "Any New method that is being considered for routine testing, and is FDA-cleared and approved, must be subject to a verification of performance specifications study including accuracy, precision and reportable range". 2. On January 16, 2025 at 12:15 pm, TS#3 was unable to provided performance specifications records for 1 of 2 QuantStudio 7500 DX instrument, serial #287881034, used to analyze Measles and Mumps viruses before use in 2024. 3. Approximately 20 Measles and Mumps patients were tested on the the QuantStudio 7500 DX instrument, serial #287881034. 4. Interview with TS#3 confirmed, performance specifications were not performed on the QuantStudio 7500 DX instrument, serial number: 287881034, before used to analyze patient tests.