Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0647002	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Department Of Public Health- Springfield	825 N Rutledge St, Springfield, 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
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 review of manufacturer's instructions, laboratory online test instructions, direct observation, patient test records, and confirmed in staff interview, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport temperature conditions) per their own specifications for two of two patient specimens for Legionella testing. Findings included: 1. The manufacturer's instructions for the BinaxNOW Legionella Urinary Antigen Card (IN852050 Rev. 12 2021/01) stated, " ...Specimen Collection Urine ...Specimens may be stored at 2-8C for up to 14 days or at -10C to -20C for longer periods before testing ...When necessary, urine specimens should be shipped in leakproof containers at 2-8C or frozen ..." 2. The laboratory's online test instructions titled, "Laboratory Manual of Services" stated, "Collect in a sterile specimen container. Specimens must be shipped refrigerated or frozen" for the Legionella Urinary Antigen. The instructions failed to define a temperature range for refrigerated specimens. 3. On 11/21/2024 at 09:45 am, delivery of specimens was observed. Boxed specimens were delivered by the FedEx delivery service. Boxes were transported by laboratory personnel to the designated areas of testing. In the microbiology testing area, Testing Person #9 (as listed on the submitted CMS-209 form) opened each box. No specimen temperatures were taken. 4. Review of patient test records (02/07/2024 through 05/13/2024) for the Legionella Urinary Antigen Card test revealed the laboratory tested two patients: Patient LEG-01-

	2024; tested 02/23/2024 Patient LEG-03-2024; tested 03/22/2024 5. In an interview on 11/21/2024 at 09:50 am, Testing Person #9 was asked if specimen receipt temperatures were monitored or documented. She stated the laboratory did not take specimen temperature upon receipt. 47517 II. Based on review of laboratory procedure, laboratory online test instructions, direct observation, patient test records, and confirmed in staff interview, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport temperature conditions) per their own specifications for ten of ten patient specimens for Influenza SARS-COV-2 Multiplex rRT-PCR testing. Findings included: 1. The laboratory's standard operating procedures titled, "Detection of Influenza A, Influenza B, and Sars-Cov-2 by Multiplex Real-Time RT-PCR (CDC Influenza SARS-CoV-2 Multiplex rRT-PCR) section 3.6.1 stated, specimens must be received cold (2-8C)." 2. The laboratory's online test instructions titled, "Laboratory Manual of Services Instructions for Influenza Virus Specimen Submission" stated, "Specimens must be maintained at 2C - 8C at all times following collection and during shipment." 3. On 11/21/2024 at 09:43 am, delivery of specimens was observed. Boxed specimens were delivered by the FedEx delivery service. Boxes were transported by laboratory personnel to the designated areas of testing. In the molecular testing area, Testing Person #8 (as listed on the submitted CMS-209 form) opened each box. No specimen temperatures were taken. 4. Review of patient test records on for the Influenza SARS-COV-2 Multiplex rRT-PCR testing test revealed the laboratory tested 10 patients and did not take specimen temperature upon receipt (11/21/2024): Accession #: S240057791 S240057242 S240057788 S240057146 S240057798 S240057786 S240057145 S240057796 S240057782 S240057144 5. In an interview on 11/21/2024 at 09:50 am, Technical Supervisor #2 was asked if specimen receipt temperatures were monitored or documented. He stated the laboratory did not take specimen temperature upon receipt.
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, laboratory temperature logs, and confirmed in staff interview, the laboratory failed to follow its own laboratory procedure for ten of ten months reviewed. 1. The laboratory's standard operating procedures titled "Real-Time Polymerase Chain Reaction (RT-PCR) for Plasmodium species, stated the following: " ...3.5.1 All blood specimens are stored at 4C for four months ...4.3.1 DNA samples should be stored at 4C until testing ...4.3.2 Primers and probes ...The reagents are aliquoted in small volumes at the molarities shown in Appendix 1.7 and stored at -20C and discarded after the log expiration date is exceeded." 2. Review of laboratory temperature logs from January 2024 to October 2024 logs revealed: a. Specimen storage refrigerator acceptable range 2-8C. Location 3550-B b. Freezer specimen and primers and probes -20C +/-5C. Location 3550-B Thermometers 230631023 and 230631018. 3. In an interview on 11/20/2024 at 2:55 pm, Technical Supervisor #2 confirmed that the laboratory procedure did not align with laboratory temperature logs.

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: Based on direct observation, review of manufacturer's instructions, laboratory procedure, gram stain records, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for gram stains for 15 of 15 testing events. Findings included: 1. During a tour of the Clinical Microbiology area (Room 3650) on 11/20/2024 at 02:40 pm, Remel Gram Crystal Violet, Remel Gram Iodine, Remel Decolorizer, and Remel Gram Safranin reagent stains were observed to be in use for gram stain testing. 2. The manufacturer's instructions for each stain stated, " ...10. Procedure ...10.2 Place the slide on a staining rack and overlay with Gram Crystal Violet for 1 minute. 10.3 Wash thoroughly with water and overlay with Gram Iodine mordant for 1 minute. 10.4 Flood with Gram Decolorizer until the solvent flows colorless from the slide (10-30 seconds). 10.5 Rinse with water and overlay with Gram Safranin for 30 seconds ..." 3. The laboratory procedure titled, "Standard Operating Procedure for the Isolation and Identification of Vibrio and Yersinia species Causing Gastroenteritis" stated, " ...6.3.3.2.1.5 Flood smear with Gram Crystal Violet, let stand for 1 minute. Wash smear thoroughly with tap water and drain off excess water. 6.3.3.2.1.6 Flood smear with Gram's Iodine, let stand 1 minute. Wash smear thoroughly with tap water and drain off excess water. 6.3.3.1.7 Decolorize until solvent running from slide is colorless (no more than 5 seconds). Be careful not to over-decolorize or under-decolorize the slide. 6.3.3.2.1.8 Wash the slide with cold tap water. 6.3.3.2.1.9 Flood smear with Gram Safranin, let stand 20 seconds. Wash thoroughly with tap water ..." The laboratory procedure stated to wash smear with tap water after Gram iodine step. This does not follow manufacturer's instructions. The laboratory procedure stated to decolorize for no more than 5 seconds. This does not follow manufacturer's instructions (10-30 seconds). The laboratory procedure stated to flood smear with Gram Safranin and let stand for 20 seconds. This does not follow manufacturer's instructions (30 seconds). 4. Review of the laboratory's gram stain records (09/08/2023 through 09/04/2024) revealed the following fifteen testing events: 09/08/2023; 10/24/2023; 12/14/2023; 01/03/2024; 01/30/2024; 02/06/2024; 02/08/2024; 03/06/2024; 05/09/2024; 05/15/2024; 05/20/2024; 05/22/2024; 06/06/2024; 07/03/2024; 09/24/2024 5. In an interview on 11/20/2024 at 03:34 pm in the conference room, Technical Supervisor #1 (as listed on the submitted CMS-209 form) confirmed the laboratory's procedure did not follow manufacturer's instructions. Technical Supervisor #1 was asked to provide studies to support the change in procedure. No documentation was provided.
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 observations, review of reagent manufacturer's instructions, laboratory environmental logs, and staff interview, the laboratory failed to ensure room temperature ranges met manufacturer's specifications for 10 of 10 months in 2024. Findings included: 1. During a tour of the Clinical Microbiology area (Room 3650) on 11/20/2024 at 02:40 pm, the following reagents were observed in use: One bottle Remel Gram Crystal Violet; Lot number 137768; Expiration Date 07/03/2025 One bottle Remel Gram Iodine; Lot number 138413; Expiration Date 07/26/2025 One bottle Remel Decolorizer; Lot number 138494; Expiration Date 07/27/2025 One bottle Remel Gram Safranin; Lot number 137771; Expiration Date 07/11/2025 Two boxes Remel RapID Inoculation Fluid; Lot number 810428; Expiration Date 03/02 /2026 One box Remel RapID Inoculation Fluid; Lot number 100268; Expiration Date 03/17/206 One box Remel Tryptic Soy Broth; Lot number 181020; Expiration Date 09 /30/2025 One box Remel Tryptic Soy Broth; Lot number 105652; Expiration Date 04 /01/2025 One box Remel Tryptic Soy Broth; Lot number 135213; Expiration Date 06 /13/2025 2. Review of the manufacturer's instructions, indicated on each reagent's label, revealed the following room temperature storage requirements: Remel Gram Crystal Violet; 20-25C Remel Gram Iodine; 20-25C Remel Decolorizer; 20-25C Remel Gram Safranin; 20-25C Remel RapID Inoculation Fluid; 20-25C Remel Tryptic Soy Broth; 2-25C 3. Review of the laboratory's environmental record titled, "Room Temperature/Relative Humidity Log" for Room 3650 from January 2024 through October 2024 revealed an acceptable room temperature range of 16-30C. This range exceed the reagents manufacturer's upper room temperature specification of 25C. 4. In an interview on 11/20/2024 at 2:50 pm, the laboratory manager, after review of the manufacturer's specifications, confirmed the finding. 47517 II. Based on direct observations, review of reagent manufacturer's instructions, laboratory environmental logs, and staff interview, the laboratory failed to ensure room temperature ranges met manufacturer's specifications for 4 of 4 months reviewed in 2024. Findings included: 1. During a tour of the Molecular testing area on 11/20/2024 at 02:45 pm, the following reagents were observed in use: Four boxes QIAamp DNA Blood Mini Kit; lot number 61904; expiration date 06/01/2025 One bottle inventrogen 1M Tris pH 8.0; Lot 00945491; expiration date N/A Two boxes QIAamp Viral RNA Mini Kit Catalog Number 52906; expiration date N/A One MagMAX Viral/Pathogen Elution Buffer; lot number 2967902; expiration date 04-30-2026 2. Review of the manufacturer's instructions, indicated on each reagent's label, revealed the following room temperature storage requirements: QIAamp DNA Blood Mini Kit; 15-25C Inventrogen 1M Tris pH 8.0; 15-25C QIAamp Viral RNA Mini Kit Catalog Number 52906; 15-25C MagMAX Viral/Pathogen Elution Buffer; 15-25C 3. Review of the laboratory's environmental record titled, "Room Temperature/Relative Humidity Log" for Molecular Room number 3538 from July 2024 through October 2024 revealed an acceptable room temperature range of 15-30C. This range exceeds the reagents manufacturer's upper room temperature specification of 25C. 4. In an interview on 11 /20/2024 at 2:55 pm, Technical Supervisor #2 confirmed the finding.