

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0647032	(X3) Date Survey Completed 04/04/2025
Name of Provider or Supplier Illinois Department Of Public Health - Carbondale	Street Address, City, State 1155 S Oakland Street, Carbondale, 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	A recertification survey conducted April 1 through April 3, 2025. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory procedure, patient records, and interview with the laboratory manager and technical supervisor #3 (TS #3), the laboratory failed to follow written laboratory procedures for one of eight patient test reports. Findings include: 1. Direct observation on 04/01/25 at 9:35 am during a laboratory tour, revealed the laboratory performed Influenza SARS-CoV-2 Multiplex RT PCR (Reverse Transcription Polymerase Chain Reaction) using the ABI (Applied Biosystems Instrument) 7500 DX analyzer. 2. The laboratory's procedure titled, "Clinical Quality Manual" section, "6.8 Specimen Submission, Handling and Referral" stated the following: a. "6.8.2.3.2. Any packages received outside of required temperature requirements, including irretrievable specimens (See list of examples of irretrievable specimens in Section 11.):" b. "6.8.2.3.2.1. Perform the assay and include the following comment, "Specimen was received outside of recommended shipping temperature range, which may affect the final results. Please correlate clinically and re-collect if necessary." 3. A review of patient requisitions and final patient reports from 03/03/24 through 01/24/25 revealed the laboratory failed to follow the laboratory's procedure for one of eight patient reports: a. Patient (#D250005228) requisition - laboratory documented, "20.7 C Out of Range" for a specimen collected on 1/14/25 and received in the laboratory on 01/15/25. b. Patient</p>

(#D25005228) final report - revealed no comment for specimens received outside of the recommended shipping temperature range. The laboratory failed to follow their own written procedure to include a comment when a specimen was received outside of required temperature requirements. 4. In an interview on 04/02/25 at 11:45 am, TS #3 confirmed the findings above.

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 direct observation, review of manufacturer's instructions, laboratory policy, laboratory environmental records, and confirmed in staff interview, the laboratory failed to ensure room temperature was within manufacturer's requirements for seven of seven boxes of Aptima Assay Fluid. Findings included: 1. During a tour of the laboratory area on 04/01/2025 at 9:08 am in the hallway, seven boxes of Aptima Assay Fluids was observed. Five boxes; Lot number 912334; expiration date 01/15 /2027 Two boxes; Lot number 904716; expiration date 09/15/2026 2. The manufacturer's instructions, indicated on the box label, stated a storage temperature of 15 - 30C for the Aptima Assay Fluids. 3. The laboratory policy titled "Clinical Quality Manual" (DCA001-26-1224) stated " ...7.3 Reagent, Standard, and Specimen Storage ...Storage of reagents and standards must be consistent with the manufacturer's instructions, if provided ..." 4. Review of the laboratory's environmental monitoring logs revealed the laboratory did not monitor and document room temperature in the hallway and failed to ensure the room temperature was within manufacturer's specifications for the Aptima Assay Fluid. 5. In an interview on 04/02/2025 at 8:30 am, the Laboratory Manager was asked to provide documentation of room temperature monitoring in the hallway. No documentation was provided. The Laboratory Manager confirmed that the hallway was not temperature monitored.

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 direct observation, review of laboratory procedure, laboratory records, and interview with the laboratory manager, the laboratory failed to perform comparison studies on two different analyzers used to perform LRN (Laboratory Response Network) testing at least twice a year for one of one year (2024). Findings include: 1.

Direct observation on 04/01/25 at 9:45 am during a laboratory tour, revealed the laboratory performs LRN testing using two ABI (Applied Biosystems Instrument) 7500 DX PCR (Polymerase Chain Reaction) analyzers interchangeably: a. ABI 7500 DX (ABI #3) b. ABI 7500 DX (ABI #4) 2. The laboratory's written procedure titled, "Clinical Quality Manual" section, "7.11. Comparison of Test Results" stated the following: a. "7.11.1 Laboratories performing the same test using different methodologies (distinct analytical, chemical, biochemical, molecular etc. techniques or kits) or instruments must have a system that, at least every six months, evaluates and defines the relationship between test results using different methodologies or instruments." 3. Record review from January 2024 through December 2024 revealed one comparison study was performed for the ABI 7500 DX PCR instruments on 04/23 /2024. 4. In an interview on 04/01/25 at 2:50 pm, the laboratory manager confirmed the laboratory performed one comparison study between January 2024 through December 2024 on the ABI 7500 DX.