Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2309727	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lightning Diagnostics	514 S Woodbine Rd, Saint Joseph, MO	

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
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: Based on review of the "Cedia Buprenorphine II Assay Calibrators and Controls" package insert, observation of refrigerator, and interview with the testing personnel (TP) #1, the laboratory failed to document open and expiration dates on Cedia Buprenorphine calibrator and controls. Findings: 1. Review of the "Cedia Buprenorphine II Assay Calibrators and Controls" package insert states "Once opened the calibrators and controls are stable for 60 days when stored 2-8 degrees Celsius". 2. Observation of the refrigerator showed Cedia Buprenorphine II Assay controls level II low lot number 7513849 in use with no open or expiration date. 3. Observation of the refrigerator showed Cedia Buprenorphine II Assay controls level II high lot number 75138050 in use with no open or expiration date. 4. Observation of the refrigerator showed Cedia Buprenorphine II Assay calibrator level II lot number 75302268 in use with no open or expiration date. 5. Observation of the refrigerator showed Cedia Buprenorphine II Assay negative calibrator level II lot number 75302152 in use with no open or expiration date. 6. Interview with the TP #1 on March 25, 2024 at 10:00 AM confirmed the laboratory failed to document open and expiration dates on Cedia Buprenorphine calibrator and controls.
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: Based on review of the Indiko Plus toxicology screening analyzer quality control (QC) records, and interview with the testing personnel (TP) #1, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results. Findings: 1. Review of the Indiko Plus toxicology screening analyzer QC records showed the laboratory used unassayed thermo scientific QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative toxicology screening QC for the analytes creatinine, Ph and cannabinoids. 4. Interview with the TP #1 on March 25, 2025 at 10:00 AM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
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 the "Lighthouse Lab Services EIA Custom level 1 and 2 Controls" package insert, review of the Indiko Plus toxicology screening analyzer quality control (QC) for 3 of 11 analytes, and interview with the testing personnel (TP) #1, the laboratory failed to ensure QC was acceptable before reporting patients results for the analytes ethanol, THC and benzodiazipine. Findings: 1. Review of the "Lighthouse Lab Services EIA Custom level 1 and 2 Controls" package insert revealed: ethanol level 1 QC range 41-68 ng/mL THC level 1 QC range 15-26 ng/mL benzodiazepine level 2 QC range 284-473 ng/mL 2. Review of the Indiko Plus toxicology screening analyzer revealed: ethanol level 1 QC 40-69 ng/mL THC level 1 QC range 7-35 ng/mL benzodiazipine level 2 QC range 284-474 3. Interview with the testing personnel (TP) #1 on March 25, 2025 at 1:30 PM confirmed the laboratory failed to ensure QC was acceptable before reporting patient results for ethanol, THC and benzodiazipine.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

	This STANDARD is not met as evidenced by: Based on review of the "Lighthouse Lab Services EIA Custom level 1 and 2 Controls" package insert, observation of the freezer and interview with the testing personnel (TP) #1, the laboratory director failed to ensure manufacturer's instructions were followed for storage of control materials. Findings: 1. Review of the "Lighthouse Lab Services EIA Custom level 1 and 2 Controls" package insert stated "Store the Level 1 and Level 2 control material at -10 to -40 degrees Celsius. Each control is stable to the expiration data printed on the vial label. Each control is stable for 30 days upon thawing and should then be stored at 2-8 degrees Celsius". 2. Observation of the freezer showed Lighthouse Lab Services EIA Custom level 1 and 2 Controls frozen and been in use. 3. Interview with TP #1 stated they thawed out controls, ran the controls on the analyzer and then refroze the controls. 4. Interview with TP #1 on March 25, 2025 at 1:30 PM confirmed the laboratory director failed to ensure the manufacturer's instructions were followed for storage of control materials.