Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2242011	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ak Diagnostic Laboratory Llc	35540 W Michigan Avenue, Wayne, MI	

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 initial certification survey was performed on February 18, 2025 at AK Diagnostic Laboratory LLC by the State of Michigan Licensing and Regulatory Affairs Department. During the survey, ti was determined Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: 493.1100 Condition: Facility administration. 493.1213 Condition: Toxicology. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor. 493.1459 Condition: Laboratories performing high complexity testing; general supervisor. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to have a sink in the laboratory space to wash hands and clean glassware (refer to D3001) and failed to have sufficient reagents to perform its to perform its liquid chromatography-mass spectrometry (LCMS) urine toxicology testing (refer to D3007).
D3001	FACILITIES CFR(s): 493.1101(a)(1) (a) The laboratory must be constructed, arranged, and maintained to ensure the following: (a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with office personnel, the laboratory failed to have a sink in the laboratory space to wash hands and clean glassware for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. The surveyor observed the laboratory on 2/18/25 at 10:25 am and noticed there was no sink anywhere in the laboratory suite. There were reusable glass containers with reagents on two of the Schimadzu toxicology analyzers, glass volumetric flasks, and a glass graduated cylinder. 2. A review of the laboratory's "Mix Diluent Procedure" revealed the laboratory uses glass volumetric flasks and amber glass screw-capped vials routinely in making reagents. 3. An interview on 2/18/25 at 10:25 am with the office personnel confirmed the laboratory does not have a sink.
D3007	FACILITIES CFR(s): 493.1101(b) (b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with office personnel, the laboratory failed to have sufficient reagents to perform its liquid chromatography-mass spectrometry (LCMS) urine toxicology testing when observed on 2/18/25. Findings include: 1. A review of the laboratory's "Reagents and Chemicals" policy revealed a list of reagents. The list included "Isopropanol (LC/MS)" and included the statement "All the solvents should be LCMS grade products." 2. The surveyor observed the laboratory's reagent storage on 2/18/25 at 10:43 am. There was a lack of LCMS-grade isopropanol. The only isopropanol present was a bottle of "70% Isopropyl Alcohol" listing its uses as "First Aid Antiseptic" and "For Rubbing & Massaging." 3. A review of the laboratory's "Standards" procedure revealed a section stating, "Reference standards and the corresponding surrogate internal standards (SIS) obtained from Cerilliant (Round Rock, TX). Should store -18 to -24 degrees C in screw capped amber glass vials labeled with analyte name, concentration, and date of opened." 4. The surveyor observed the laboratory's freezer on 2/18/25 at 10:54 am revealed a lack of standards used to make the laboratory's calibration and control materials. 5. An interview on 2/18/25 at 2:31 pm with the office personnel confirmed the lack of isopropanol and standards present in the laboratory.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to establish policies and procedures to include urine specimen collection and transportation conditions (refer to D5311), failed to date approved procedures before

	use (refer to D5407), failed to ensure the room temperature conditions were within the laboratory's criteria for proper storage (refer to D5413), failed to label its controls and calibrators with the preparation and expiration dates (refer to D5415), failed to ensure reagents used in urine toxicology testing had not exceeded expiration dates (refer to D5417), failed to establish performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include analytical sensitivity prior to testing patients (refer to D5423 A), failed to establish performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include specimen storage and stability prior to testing patients (refer to D5423 B), failed to have documentation of the instrumentation measurements used in the laboratory's establishment of performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system (refer to D5427 A), failed to have the reference laboratory test reports used to establish accuracy performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system (refer to D5427 B), failed to perform and document calibrations for its urine toxicology testing (refer to D5437), failed to establish criteria and statistical parameters for each batch of control materials prior to use in urine toxicology testing (refer to D5469), and failed to perform corrective action for patients tested when controls failed (refer to D5783).
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: . Based on record review and interview with the general supervisor, the laboratory failed to establish policies and procedures to include urine specimen collection and transportation conditions for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of urine specimen collection and conditions for transportation policies and procedures. 2. An interview on 2/18/25 at 4:49 pm with the general supervisor confirmed the laboratory had not established urine specimen collection and conditions for transportation policies and procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel, the laboratory director failed to date approved procedures before use for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review

	of the procedure manual revealed the laboratory director had not dated the test procedures. 2. A review of the "Preparation of Dilutant Mixture" showed the laboratory is to use and the "Mix Diluent Procedure" revealed differing processes to make the same diluent used in urine toxicology testing. Neither procedure included the date. 3. An interview on 2/18/25 at 2:31 pm with the office personnel confirmed the laboratory director had not dated procedures prior to use.
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 observation, record review, and interview with office personnel, the laboratory failed to ensure the room temperature conditions were within the laboratory's criteria for proper storage for nine of nine total temperature readings. Findings include: 1. The surveyor observed the thermometer reading for room temperature was 17.9 degrees C near the Schimadzu toxicology analyzers on 2/18/25 at 9:24 am. 2. A review of the laboratory's "Mobile Phase A" and "Mobile Phase B" policies for reagents on the Schimadzu toxicology analyzers revealed the storage temperature range was "20-25 degrees C." 3. A review of the laboratory's room temperature log revealed the following dates when temperatures were out of range: a. 2/3/25 19.0 degrees C b. 2/4/25 18.0 degrees C c. 2/5/25 18.7 degrees C d. 2/6/25 18.9 degrees C e. 2/10/25 18.5 degrees C f. 2/11/25 18.9 degrees C g. 2/12/25 18.1 degrees C h. 2/13/25 19.7 degrees C i. 2/14/25 18.9 degrees C 4. An interview on 2/18/25 at with the office personnel confirmed the laboratory room temperature was out of range.
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 observation and interview with office personnel, the laboratory failed to label its controls and calibrators with the preparation and expiration dates for 13 microcentrifuge tubes observed. Findings include: 1. The surveyor observed three control materials and 10 calibrators in microcentrifuge tubes lacking preparation and expiration dates on 2/18/25 at 10:54 am. 2. A review of the laboratory's "Labeling Policy & Procedure" revealed a lack of reagent labeling requirements. 3. An interview

	on 2/18/25 at 10:54 am with the office personnel confirmed the 13 microcentrifuge tubes lacked preparation and expiration dates.
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 observation and interview with office personnel, the laboratory failed to ensure reagents used in urine toxicology testing had not exceeded expiration dates for three of six reagent bottles on the Schimadzu toxicology analyzers. Findings include: 1. The surveyor observed the Schmadzu toxicology analyzers. The instrument on the right side had the following reagents on board: a. Ammonium Acetate, 0.41g Ammonium Acetate, 100 mL LCMS water with the preparation date of 12/13/24 and the expiration date of 12/23/24. b. 75% Methanol with the preparation date of 12/13 /24 and the expiration date of 12/23/24. c. 100% Acetonitrile with the preparation date of 12/13/24 and the expiration date of 12/23/24. 2. A review of patient test records and quality control records revealed a lack of information about which analyzer was used to perform testing. 3. An interview on 2/18/25 at 2:31 pm with the office personnel confirmed the reagents were expired.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the general supervisor, the laboratory failed to establish performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include analytical sensitivity prior to testing patients for one (January 2025 to February 2025) of one month since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "LOD (Lower Limited of Detection)" revealed a section stating, "It is stablishing the dynamic range of each analyte measured within this panel. The LOD is the low concentration of the analyte can detect above the blank matrix." The documentation of the analytical sensitivity present was a list of the laboratory's analytes and the lower limit of detection values for each analyte. 2. The surveyor requested the analytical sensitivity data used to establish each of the values on 2/18/25 at 11:43 am and it was not made available. 3. An interview on 2/18/25 at 5:08 pm

	with the general supervisor revealed the laboratory used a calculation to determine analytical sensitivity rather than using measured values obtained from the test system. B. Based on record review and interview with the general supervisor, the laboratory failed to establish performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include specimen storage and stability prior to testing patients for one (January 2025 to February 2025) of one month since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Stability" performance specifications had a summary stating, "First sample spike after 24 hours 22C Room Temperature: Our study showes after one day storage under room 22C, the concentration for the compound start showing very bad accuracy percentage, also some compounds showed no concentration." The documentation of results only had records from the testing performed after 24 hours at room temperature. 2. The surveyor requested any additional specimen storage and stability study records on 2/18/25 at 11:43 am and it was not made available. 3. An interview on 2/18/25 at 5:16 pm with the general supervisor confirmed the laboratory had not performed additional specimen storage and stability studies to establish performance specifications prior to testing patients.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the office personnel, the laboratory failed to have documentation of the instrumentation measurements used in the laboratory's establishment of performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review of the laboratory's performance specifications revealed a lack of data used to determine the Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system's performance specifications. 2. An interview on 2/18/25 at 11:43 am with the office personnel confirmed the data used to support performance specifications was not accessible. B. Based on record review and interview with the general supervisor, the laboratory failed to have the reference laboratory test reports used to establish accuracy performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system for one (January 2025 to February 2025) of one month since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Accuracy Study" revealed a section stating, "6 samples prepared with different concentration and same matrix used with patients' samples. The samples ran in a reference lab and same prepared ran in AK lab. The deference between the two labs below 30%. The measurement unite was same in both labs and same method which nano gram/mL. The formula ((abs(n1-n2))n)*100." The accuracy study documentation provided was a spreadsheet including values from "AK" and "Reference Lab" and did not include reference laboratory test reports. 2. The surveyor requested the reference laboratory's test reports used in the accuracy study on 2/18/25 at 11:43 am and were not made available. 3. An interview on 2/18/25 at 5:07 pm with the general supervisor confirmed the reference laboratory test reports were not available.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel, the laboratory failed to perform and document calibrations for its urine toxicology testing for one (January 2025 to February 2025) of one month since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Quality Control Procedure" revealed a section for calibration titled "Corrective action if calibrators fails" stating, "In case the calibrator fails in any batch, and we find one or more calibrator does not match the r 0.90 or greater, then we have to do the following" showing the laboratory was to perform calibrations with each batch of patient testing. 2. The surveyor requested calibration records from January 2025 to February 2025 on 2/18/25 at 12:13 pm and documentation was not made available. 3. An interview on 2/18/25 at 12:13 pm with office personnel confirmed the calibration records were not available.
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 record review and interview with office personnel, the laboratory failed to establish criteria and statistical parameters for each batch of control materials prior to use in urine toxicology testing for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review of the laboratory's "New Reagents and Old Reagents Policy" revealed a section stating, "When reagents expire, the old set of calibrators and quality controls will be run with the new quality control set prepared from the new reagents in the same batch and the results will be compared." and "The results of the new QC results should match the old QC results with a maximum of 5 % difference. Then the new QC will be run with new calibrations prepared from the same dilutions of the new reagents for 10 consecutive

	days to establish the mean of the new QC that should be within 10% of the target." 2. The surveyor requested documentation of the establishment of acceptability criteria and statistical parameters for each batch of controls used since the laboratory started testing in January 2025 on 2/18/25 at 12:03 pm and records were not made available. 3. An interview on 2/18/25 at 12:03 pm with office personnel confirmed the laboratory had not established acceptability criteria or statistical parameters for each batch of controls used in its urine toxicology testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel, the laboratory failed to perform corrective action for patients tested when controls failed for two (1/28/25 and 2/10/25) of five testing dates reviewed. Findings include: 1. A review of the laboratory's "Quality Control Procedure" revealed a section stating, "The percentage difference between mean and +/-2SD is 26% for the low QC and 25% for the mid and high QC." 2. A review of the laboratory's quality control records and corrective action forms revealed the following dates when the laboratory determined controls were out of range: a. 1/28/25, pregabalin level one, two, and three received no results. A total of 81 patients were tested in this batch. b. 2/10/25, hydromorphone level one and two had "0" and level three had an accuracy percentage 26.08% away from the mean. A total of 72 patients were tested in this batch. 3. A review of patient test reports from the 1/28/25 and 2/10/25 runs revealed results for pregabalin, and hydromorphone were reported. 4. The surveyor requested any reruns or corrected reports issued by the laboratory as corrective action for patients reported from runs with failed controls on 2 /18/25 at 2:28 pm. 5. An interview on 2/18/25 at 2:28 pm with office personnel confirmed corrective action for patients tested with the 1/28/25 and 2/10/25 runs with failed controls was not performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory director failed to ensure the laboratory had sufficient reagents to perform its liquid chromatography-mass spectrometry (LCMS) urine toxicology testing (refer to D6079 A), failed to ensure reagents used in urine toxicology testing had not exceeded expiration dates (refer to D6079 B), failed to ensure the room temperature conditions were within the laboratory's criteria for proper storage (refer to D6083), failed to ensure there was a

	sink in the laboratory space to wash hands and clean glassware (refer to D6084), failed to ensure performance specifications were established for the Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include analytical sensitivity prior to testing patients (refer to D6085 A), failed to have documentation of the instrumentation measurements used in the laboratory's establishment of performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system (refer to D6085 B), failed to have the reference laboratory test reports used to establish accuracy performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system (refer to D6085 C), failed to ensure performance specifications were established for the Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include specimen storage and stability prior to testing patients (refer to D6085 D), failed to date approved procedures before use (refer to D6087), failed to ensure calibrations were performed and documented for its urine toxicology testing (refer to D6093 A), failed to ensure criteria and statistical parameters were established for each batch of control materials prior to use in urine toxicology testing (refer to D6093 B), failed to ensure corrective action for patients tested when controls failed was performed (refer to D6096), failed to employ a technical supervisor for its high complexity toxicology testing (refer to D6102 A), failed to have a qualified general supervisor for its high complexity toxicology testing (refer to D6102 B), and failed to have qualified testing personnel for its high complexity toxicology testing (refer to D6102 C).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with the office personnel, the laboratory director failed to ensure the laboratory had sufficient reagents to perform its urine toxicology testing. Refer to D3007 B. Based on observation and interview with the office personnel, the laboratory director failed to ensure reagents used in urine toxicology testing had not exceeded expiration dates. Refer to D5417.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by:

	. Based on observation, record review, and interview with the office personnel, the laboratory director failed to ensure the room temperature conditions were within the laboratory's criteria for proper storage. Refer to D5413.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the office personnel, the laboratory director failed to ensure there was a sink in the laboratory space to wash hands and clean glassware. Refer to D3001.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the general supervisor, the laboratory director failed to ensure performance specifications were established for the Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include analytical sensitivity prior to testing patients. Refer to D5423 A. B. Based on record review and interview with the office personnel, the laboratory director failed to have documentation of the instrumentation measurements used in the laboratory's establishment of performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system. Refer to D5427 A. C. Based on record review and interview with the general supervisor, the laboratory director failed to have the reference laboratory test reports used to establish accuracy performance specifications of its Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system. Refer to D5427 B. D. Based on record review and interview with the general supervisor, the laboratory director failed to ensure performance specifications were established for the Schimadzu liquid chromatography mass spectrometry (LCMS) urine toxicology test system to include specimen storage and stability prior to testing patients. Refer to D5423 B.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 record review and interview with the office personnel, the laboratory director failed to date approved procedures before use. Refer to D5407.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: . A. Based on record review and interview with office personnel, the laboratory director failed to ensure calibrations were performed and documented for its urine toxicology testing. Refer to D5437 A. B. Based on record review and interview with office personnel, the laboratory director failed to ensure criteria and statistical parameters were established for each batch of control materials prior to use in urine toxicology testing. Refer to D5469.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel, the laboratory director failed to ensure corrective action for patients tested when controls failed was performed. Refer to D5783.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the general supervisor, the laboratory director failed to employ a technical supervisor for its high complexity toxicology testing. Refer to D6109. B. Based on record review and a lack of documentation, the laboratory director failed to have a qualified general supervisor for its high complexity toxicology testing. Refer to D6143. C. Based on record review and a lack of documentation, the laboratory director failed to have qualified testing personnel for its high complexity toxicology testing. Refer to D6171.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

	This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor, the laboratory director failed to establish policies and procedures to include urine specimen collection and conditions for transportation. Refer to D5311.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with the general supervisor, the laboratory failed to employ a technical supervisor for its high complexity toxicology testing. Refer to D6109.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor, the laboratory failed to employ a technical supervisor for its high complexity toxicology testing for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review of the laboratory's Form CMS-209 revealed a lack of technical supervisor for its high complexity toxicology testing. 2. An interview on 2/18 /25 at 4:43 pm with the general supervisor revealed the laboratory had not employed a technical supervisor.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to have a qualified general supervisor for its high complexity toxicology testing (refer to D6143) and the general supervisor failed to ensure corrective action was performed for patients tested when controls failed (refer to D6150).
D6143	GENERAL SUPERVISOR QUALIFICATIONS

	CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g). This STANDARD is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to have a qualified general supervisor for its high complexity toxicology testing for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review of the general supervisor's qualifications revealed a lack of documentation showing they met testing personnel qualifications under 493.1489(b)(3), to qualify as a general supervisor under 493.1461(c)(2). 2. The surveyor requested additional qualification records on 2/18/25 at 9:08 am and 4:44 pm and they were not made available. 3. The laboratory was given an additional two days to provide the missing documentation, and it was not received.
D6150	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(2) (b)(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

	This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel, the general supervisor failed to ensure corrective action was performed for patients tested when controls failed. Refer to D5783.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to have qualified testing personnel for its high complexity toxicology testing (refer to D6171), testing personnel failed to ensure criteria and statistical parameters for each batch of control materials was established prior to use in urine toxicology testing (refer to D6177 A), failed to ensure criteria and statistical parameters for each batch of control materials was established prior to use in urine toxicology testing (refer to D6177 B), testing personnel failed to follow policies to perform corrective action for patients tested when controls failed (refer to D6178), and testing personnel failed to ensure reagents used in urine toxicology testing had not exceeded expiration dates (refer to D6179).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

	(b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to have qualified testing personnel for its high complexity toxicology testing for one (January 2025 to February 2025) of one month since the laboratory started testing. Findings include: 1. A review of the testing personnel's qualifications revealed a lack of completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP or at least three months documented laboratory training in each specialty in which the individual performs high complexity testing. 2. The surveyor requested additional qualification records on 2/18/25 at 9:08 am and 4:44 pm and they were not made available. 3. The laboratory was given an additional two days to provide the missing documentation, and it was not received.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) (b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: . A. Based on record review and interview with office personnel, the testing personnel failed to ensure criteria and statistical parameters for each batch of control materials were established prior to use in urine toxicology testing. Refer to D5469. B. Based on record review and interview with office personnel, the testing personnel failed to perform and document calibrations for its urine toxicology testing. Refer to D5437.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) (b)(4) Follow the laboratorys established policies and procedures whenever test systems are not within the laboratorys established acceptable levels of performance; This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel, the testing personnel failed to follow policies to perform corrective action for patients tested when controls failed. Refer to D5783.
D6179	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(5)

	(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director; This STANDARD is not met as evidenced by: . Based on observation and interview with the office personnel, the testing personnel failed to ensure reagents used in urine toxicology testing had not exceeded expiration dates. Refer to D5417.