Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2190193	01/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
New Oakland Family Centers	26545 America Drive, Southfield, 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
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, review of records, and interviews, the laboratory failed to follow its competency assessment policies to ensure testing personnel competency (refer to D5209), failed to verify the accuracy of 41 of its 123 analytes at least twice annually (refer to D5217), failed to evaluate proficiency testing and perform and document corrective actions when results were unacceptable (refer to D5221), failed to follow written procedures for lot-to-lot verification of its calibration materials (refer to D5401), failed to label solutions with the preparation and expiration dates (refer to D5415), failed to establish performance specifications for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer (refer to D5423 A), failed to establish performance specifications for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer to include specimen collection devices, specimen storage, and specimen stability prior to performing patient testing (refer to D5423 B), laboratory failed to establish maintenance protocols to clean its reusable glassware and measuring devices (refer to D5433), failed to perform and document calibrations for its quantitative urine toxicology testing (refer to D5439), failed to perform and document quality control testing for its quantitative urine toxicology testing (refer D5445), used the same materials for controls and calibrators on the AB Sciex Triple Quad 4500 analyzer (refer to D5467), failed to follow written procedures for lot-to-lot verification of its control materials (refer to D5469), failed to perform corrective action when results controls failed to meet acceptability criteria (refer to D5783), failed to include the test result and units of measurement for urine creatinine

	adulterant testing on test reports (refer to D5805), and failed to include the reference range for urine creatinine adulterant testing on test reports (refer to D5807).
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: . Based on record review and interview with the Technical Supervisor, the laboratory failed to follow its competency assessment policies to ensure testing personnel competency for one (Testing Personnel #1) of two testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Competency Assessment Policy" revealed a section stating, "Competency is evaluated during on-the-job training, proficiency testing, and randomly during the technical audits of test methods. Competency is assessed and documented at initial evaluation, six-month evaluation, annual evaluation and every year after that." 2. A review of Testing Personnel #1's competency assessment records revealed the most recent competency assessment performed in August 2023, prior to the implementation of the ABSciex Triple Quad 4500 instrumentation in November 2023 and the Carolina Liquid Chemistries CLC 800 in September 2024. 3. An interview on 1/14/25 at 4:28 pm with the Technical Supervisor confirmed competency assessments for Testing Personnel #1 were not performed in accordance with the laboratory's procedure.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to verify the accuracy of 41 of its 123 analytes at least twice annually for two (January 2023 to January 2025) of two years reviewed. Findings include: 1. A review of the laboratory's proficiency testing revealed the laboratory was enrolled in the College of American Pathologists' (CAP) Drug Monitoring for Pain Management events in 2023 and 2024. The following are the analytes on the laboratory's test menu, but are not challenged by the CAP proficiency testing event: urine creatinine ethanol amitriptyline aripiprazole atomoxetine bupropion busprione carbamazepine citalopram clomipramine clonidine closapine cyclobenzaprine doxepine duloxetine fluoxetine haloperidol ketamine lamotrigine lurasidone meperidine methylphenidate mirazepine mitragynine naloxone naltrexone nortriptyline olanzapine oxcarbazepine paroxetine PCP phentermine quetiapine resperidone ritalinic acid sertraline topiramate venlafaxine ziprasidone zolpidem 2. An interview on 1/14/25 at 2:24 pm with the Technical Supervisor revealed the laboratory had not verified the accuracy of its analytes not challenged with the CAP proficiency testing event at least twice annually from January 2023 to Janaury 2025.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to evaluate proficiency testing and perform and document corrective actions when results were unacceptable for one (2024 DMPM-A) of four testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records from the last four testing events with the College of American Pathologists' Drug Monitoring for Pain Management (DMPM) revealed an unacceptable score for buprenorphine testing on the 2024 DMPM-A event. 2. An interview on 1/14/25 at 2: 45 pm with the Technical Supervisor revealed corrective action had not been performed for the unacceptable results and the event had not been evaluated for errors.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 record review and interview with the Technical Supervisor, the laboratory failed to follow written procedures for lot-to-lot verification of its calibration materials for two (January 2023 to January 2025) of two years reviewed. Findings include: 1. A review of the laboratory's "Lot-to-Lot Verification" policy revealed a section titled "Calibrators" stating, "Each new lot of calibrator is verified by assaying as patient samples (5x) using the new lot of calibrators and current lot of reagents. Quality control results of the analytical run must meet acceptance criteria for the new lot to be accepted. New calibrator lots are verified for acceptable performance prior to depletion of the present lot. The calculated mean of all confirmation results must be within +20% of the nominal (target) concentration. The target is accepted as the calibrator concentration." 2. The surveyor requested documentation of lot-to-lot verification for the laboratory's calibrators between January 2023 and January 2025 on 1/14/25 at 11:43 am and documentation was not provided. 3. An interview on 1/14/25 at 11:53 am with the Technical Supervisor confirmed the laboratory had not performed lot-to-lot verifications for calibrators between January 2023 and January 2025.
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 the Technical Supervisor, the laboratory failed to label solutions with the preparation and expiration dates for four containers observed. Findings include: 1. The surveyor observed four plastic urine containers in the laboratory refrigerator labeled "H2O", "M.Mix", "Neg urine", and "MeOH" without preparation and expiration dates on 1/14/25 at 8:56 am. 2. An interview on 1 /14/25 at 9:08 am with the Technical Supervisor confirmed the containers listed above were not labeled to include preparation and expiration dates.
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 Technical Supervisor, the laboratory failed to establish performance specifications for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer for 14 (November 2023 to January 2025) of 14 months the laboratory had been using the system to test patient specimens. Findings include: 1. A review of the laboratory's data for the ABSciex Triple Quad 4500 analyzer establishment of performance specifications revealed the names of personnel not listed on Form CMS-209. 2. An interview on 1/14/25 at 9:43 am with the Technical Supervisor revealed the studies for the establishment of performance specifications from November 2023 were not performed with the laboratory's staff, but were instead performed by a contracted third party. B. Based on record review and interview with the Technical Supervisor, the laboratory failed to establish performance specifications for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer to include specimen collection devices, specimen storage, and specimen stability prior to performing patient testing for 14 (November 2023 to January 2025) of 14 months the laboratory had been using the system. Findings include: 1. A review of the laboratory's establishment of performance specifications revealed a lack of specifications for specimen collection devices, specimen storage, and specimen stability prior to the initiation of patient testing in November 2023. 2. A review of the "Stability Studies" document dated 1/11/25 by the Laboratory Director stated, "Method: One set of calibrators (level 1-6, including negative calibrator) and quality controls (3 levels of controls- low, medium, and high) were tested. They were stored in the refrigerator at 2-8 degrees C. They were tested everyday for almost 2 weeks." 3. An interview on 1/14/25 at 10:03 am with the Technical Supervisor confirmed the study was performed after the laboratory had started testing patients and not performed with urine specimens in the collection cups used by the laboratory.
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Technical Supervisor, the laboratory failed to establish maintenance protocols to clean its reusable glassware or measuring devices for two (January 2023 to January 2025) of two years reviewed. Findings include: 1. The surveyor observed the laboratory using glass containers to hold reagents attached to the laboratory's ABSciex triple Quad 4500 on 1/14/25 at 8: 56 am. 2. A review of the laboratory's policies and procedures revealed a lack of protocol for cleaning its reusable glassware or measuring devices. 3. A review of the laboratory's "Quantitative Analysis of Presciption and Illicit Drugs in Human Urine by Liquid Chromatography-Tadem Mass Spectrometry (LCMSMS)" procedure revealed a section stating, "Use class A glass volumentric flasks with stoppers and follow dilution instructions." 4. An interview on 1/14/25 at 4:04 pm with the Technical Supervisor confirmed the laboratory had not established a process for cleaning its glassware or reusable measuring devices and has not cleaned its glassware when replenishing reagents on the ABSciex Triple Quad 4500 analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to perform and document calibrations for its quantitative urine toxicology testing for 11 (January 2023 to November 2023) of 24 months reviewed. Findings include: 1. The surveyor requested calibration results for the following testing dates and documentation of quality control performance for quantitative urine toxicology testing was not present: a. 09/19/2023 b. 06/22/2023 c. 03/13/2023 d. 01/26/2023 2. A review of the laboratory's "Quantitative Analysis of Presciption and Illicit Drugs in

	Human Urine by Liquid Chromatography-Tadem Mass Spectrometry (LCMSMS)" procedure revealed a section titled "General Guidelines for Quantitate Results in MultiQuant Software" and "Quantitation and Acceptance Criteria" stating, "Calibration Curve: a. R value must be greater than 0.985 b. No more than two out of six points may be excluded c. All included standards must have an accuracy between 80% and 120%, except the 50% (C/O), which must have an accuracy between 75% and 125%." 3. An interview on 1/14/25 at 4:01 pm with the Technical Supervisor revealed the laboratory did not have documentation of calibrations performed prior to November 2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to perform and document quality control testing for its quantitative urine toxicology testing for 11 (January 2023 to November 2023) of 24 months reviewed. Findings include: 1. The surveyor requested quality control testing results for the following testing dates and documentation of quality control performance for quantitative urine toxicology testing was not present: a. 09/19/2023 b. 06/22/2023 c. 03/13/2023 d. 01/26/2023 2. A review of the laboratory's "Quality Control" policy revealed a section titled "LCMS" stating, "Daily verify that QCs values are within allowable ranges (within 20%). There are 2 sets of 3 levels of QCs ran with every batch of patient samples." 3. An interview on 1/14/25 at 4:28 pm with the Technical Supervisor revealed the laboratory did not have documentation of quality control testing performed prior to November 2023.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) (d)(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. This STANDARD is not met as evidenced by: . Based on record review, observation, and inteview with the Technical Supervisor, the laboratory used the same materials for controls and calibrators on the AB Sciex Triple Quad 4500 analyzer for 14 (November 2023 to January 2025) of 14 months since the laboratory implemented the AB Sciex Triple Quad 4500 analyzer. Findings include: 1. A review of the laboratory's "Quantitative Analysis of Prescription and Illicit Drugs in Human Urine by Liquid Chromatography-Tandem Mass Spectrometry

	(LCMSMS)" procedure revealed a section titled "Calibration Curve Stock/QC Solution Preparation" stating, "Calibration curve levels and quality control levels share the same method preparation from different stock lot number or another technologist to adhere to Quality Management rules." 2. A review of the laboratory's "Quantitative Analysis of Prescription and Illicit Drugs in Human Urine by Liquid Chromatography-Tandem Mass Spectrometry (LCMSMS)" procedure revealed a section titled "Preparation of Working Calibration and Quality Controls" revealed a table showing the calibration curve stock solution is used in making both calibration and controls materials. The level five calibrator has the same concentration as the level three control material (eight times the cutoff) and the level three calibrator has the same concentration as the level two control material (two times the cutoff). 3. The surveyor observed the calibration curve stock solution and the quality control stock solution in the freezer on 1/14/25 at 9:08 am. No lot numbers were indicated on either solutions. 4. An interview on 1/14/25 at 10:48 am with the Technical Supervisor revealed the laboratory used the same lots of materials to make calibrators and controls. 5. An interview on 1/14/25 at 11:09 am with the Technical Supevisor confirmed the concentrations of the level five calibrator was the same as the level three control and the level three calibrator was the same as the level two control. 6. An interview on 1/14/25 at 11:18 am with the Technical Supervisor revealed the stock solutions used to make calibrators and control materials are made by the Technical Supervisor.
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 the Technical Supervisor, the laboratory failed to follow written procedures for lot-to-lot verification of its control materials for two (January 2023 to January 2025) of two years reviewed. Findings include: 1. A review of the laboratory's "Lot-to-Lot Verification" policy revealed a section titled "Controls" stating, "Each new lot of control is verified by analysis (5x) using the current lot of reagents. Results for both the old QC and the new QC lot must meet acceptance cirteria for the new lot to be accepted. New control lots are verified for acceptable performance prior to depletion of the present lot." and "Each new lot of control is verified by analysis using the current lot of calibrators and QC. Results for the new QC lot must meet acceptance criteria for the new lot to be accepted. New control lots are verified for acceptable performance prior to depletion of the present lot." 2. The surveyor requested documentation of lot-to-lot verification for the laboratory's controls between January 2023 and January 2025 on 1/14/25 at 11:43 am and documentation was not provided. 3. An interview on 1/14/25 at 11:53 am with the Technical Supervisor confirmed the laboratory had not performed lot-to-lot verifications for controls between January 2023 and January 2025.

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 the Technical Supervisor, the laboratory failed to perform corrective action when results controls failed to meet acceptability criteria for one (4/17/24) of 11 testing dates reviewed. Findings include: 1. A review of the laboratory's Carolina Liquid Chemistries CLC 800 qualitative urine toxicology quality control records for 11 patient testing dates revealed buprenorphine level one control fell outside of acceptability criteria on 4/17/24. A total of 14 patients had testing performed and reported. 2. The surveyor requested corrective action on 1/14 /25 at 3:34 pm for the 14 patients receiving testing on 4/17/24 and none was made available. 3. An interview on 1/14/25 at 4:10 pm with the Technical Supervisor confirmed corrective action had not been performed for patients receiving testing when control results fell outside of acceptability requirements.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to include the test result and units of measurement for urine creatinine adulterant testing on test reports for three (Patients 1-3) of 11 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed the laboratory reports urine creatinine for adulterant testing. The test reports for patients tested below do not include a unit of measurement nor a quantitative result: a. Patient #1 had urine creatinine testing reported on 12/20/24 with a result of "Negative." b. Patient #2 had urine creatinine testing reported on 8/19/24 with a result of "Negative." c. Patient #3 had urine creatinine testing reported on 6/13/24 with a result of "Negative." 2. An interview on 1/14/25 at 9:45 am with the Technical Supervisor confirmed the laboratory reports any value below 300 as negative and any value above 300 as positive, rather than reporting the numerical value to be used in determining whether the specimen was a valid urine specimen.
D5807	TEST REPORT

	CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to include the reference range for urine creatinine adulterant testing on test reports for three (Patients 1-3) of 11 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed the laboratory reports urine creatinine for adulterant testing. The test reports for patients tested below do not include aa reference range used to interpret test results: a. Patient #1 had urine creatinine testing reported on 12/20/24 with a result of "Negative." b. Patient #2 had urine creatinine testing reported on 8/19/24 with a result of "Negative." c. Patient #3 had urine creatinine testing reported on 6/13/24 with a result of "Negative." 2. An interview on 1 /14/25 at 9:45 am with the Technical Supervisor confirmed the laboratory reports any value below 300 as negative and any value above 300 as positive, rather than reporting the numerical value and reference range to be used in determining if the specimen was a valid urine specimen.
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 observation, review of records, and interviews, the Laboratory Director failed to ensure performance specifications were established by the laboratory for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer (refer to D6085 A), failed to ensure performance specifications were established for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer to include specimen collection devices, specimen storage, and specimen stability prior to performing patient testing (refer to D6085 B), failed to ensure proficiency testing was evaluated and performed and documented corrective actions when results were unacceptable (refer to D6092), failed to ensure the laboratory followed written procedures for lot-to-lot verification of its calibration materials (refer to D6095 A), failed to ensure the laboratory performed and documented calibrations for its quantitative urine toxicology testing (refer to D6095 B), failed to ensure the laboratory performed and documented quality control testing for its quantitative urine toxicology testing (refer to D6095 C), failed to ensure the laboratory had not used the same materials for controls and calibrators on the AB Sciex Triple Quad 4500 analyzer (refer to D6095 D), failed to ensure follow procedures for lot-to-lot verification of its control materials were performed (refer to D6095 E), failed to ensure verification of accuracy was performed for 41 of its 123 analytes at least twice annually (refer to D6097), failed to ensure test reports included the test result and units of measurement for urine creatinine adulterant testing (refer to D6098 A), failed ensure test reports included the reference range for urine creatinine adulterant testing

	(refer to D6098 B), and failed to ensure its competency assessment policies were followed to ensure testing personnel competency (refer to D6102). .
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 Technical Supervisor, the Laboratory Director failed to ensure performance specifications were established by the laboratory for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer. Refer to D5423 A. B. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure performance specifications were established for its laboratory-developed quantitative urine toxicology test system using the ABSciex Triple Quad 4500 analyzer to include specimen collection devices, specimen storage, and specimen stability prior to performing patient testing. Refer to D5423 B.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure proficiency testing was evaluated and performed and documented corrective actions when results were unacceptable. Refer to D5221.
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 the Technical Supervisor, the Laboratory Director failed to ensure the laboratory followed written procedures for lot-to-lot verification of its calibration materials. Refer to D5401. B. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure the laboratory performed and documented calibrations for its quantitative urine toxicology testing. Refer to D5439. C. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure the laboratory performed and documented quality control testing for its quantitative urine toxicology testing. Refer to D5445. D. Based on record review, observation, and inteview with the Technical Supervisor, the Laboratory Director failed to ensure the laboratory had not used the same materials for controls and calibrators on the AB Sciex Triple Quad

	4500 analyzer. Refer to D5467. E. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure follow procedures for lot-to-lot verification of its control materials were performed. Refer to D5469.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure verification of accuracy was performed for 41 of its 123 analytes at least twice annually. Refer to D5217.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure corrective action was performed for patients with testing report when results controls failed to meet acceptability criteria. Refer to D5783.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure test reports included the test result and units of measurement for urine creatinine adulterant testing. Refer to D5805. B. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed ensure test reports included the reference range for urine creatinine adulterant testing. Refer to D5807.
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:

	. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure its competency assessment policies were followed to ensure testing personnel competency. Refer to D5209.