Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2149322	12/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Central Medical Laboratory Llc	15230 Levan Road Level B, Livonia, 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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: . A. Based on observation and interview with the Laboratory Director, the laboratory failed to utilize a uni-directional workflow for its open-system, SARS-CoV-2 molecular test system for 1 testing run observed. Findings include: 1. The surveyor observed the Laboratory Director perform SARS-CoV-2 testing for 5 specimens using its SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler on 12/21 /22 at 9:51 am. The Laboratory Director entered the post-amplification area with the pre-amplification patient and quality control specimens to start the run on the thermocycler. Just as the Laboratory Director was about to set the pre-amplification samples in the thermocycler, he took the previous run's post-amplification samples to discard in the next room after putting the pre-amplification specimens back into the pre-amplification area. Once the post-amplification samples were disposed, the next run's pre-amplification samples were set into the thermocycler using the same gloves. 2. An interview on 12/21/22 at 1:44 pm with the Laboratory Director confirmed a unidirectional workflow had not been used for SARS-CoV-2 molecular testing. B. Based on observation and interview with the Laboratory Director, the laboratory failed to have separate areas for reagent preparation and specimen preparation for its open-system, SARS-CoV-2 molecular test system for 1 testing run observed. Findings include: 1. The surveyor observed the Laboratory Director perform SARS-CoV-2 testing for 5 specimens using its SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler on 12/21/22 at 9:51 am. The Laboratory Director utilized the same biosafety cabinet for preparing the master mix reagents and to prepare and dispense patient specimens into the reaction wells. 2. An interview on 12/21/22 at 1:

	44 pm with the Laboratory Director confirmed the laboratory utilizes the same biosafety cabinet for both reagent preparation and specimen preparation.
D3007	FACILITIES CFR(s): 493.1101(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 the Laboratory Director, the laboratory failed to have the appropriate pipettes to dispense volumes less than 10 uL for its molecular SARS-CoV-2 testing for 1 testing run observed. Findings include: 1. The surveyor observed the Laboratory Director perform SARS-CoV-2 testing for five specimens using its SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler on 12/21/22 at 9:51 am. The Laboratory Director used a Lichen pipette with a specified range of 20-200 uL to dispense the following components: a. Dye, 8 uL b. Patient sample, 5 uL c. Positive and Negative quality control, 5 uL 2. The surveyor toured the laboratory on 12/21/22 at 9:00 am and the following pipettes had been identified: a. Eppendorf Research Plus 1000 uL b. Eppendorf 200 uL c. Walter 100-1000 uL d. Walter 10-100 uL e. Lichen 20-200 uL 3. A review of the laboratory's Lichen Pipette Instructions for Use on 12/21/22 revealed a section stating, "The volume of the pipette is clearly shown through the handle grip window. The delivery volume is set by turning the thumb button clockwise or anticlockwise. When setting the volume, please make sure that: a. the desired delivery volume clicks into place. b. the digits are completely visible in the display window. c the selected volume is within the pipette's specified range." 4. An interview on 12/21/22 at 1:44 pm with the Laboratory Director confirmed the laboratory did not have the appropriate pipette to dispense volumes less than 10 uL.
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, 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 utilize a uni-directional workflow for its open-system, SARS-CoV-2 molecular test system (Refer to D3005 A), failed to have separate areas for reagent preparation and specimen preparation for its open-system, SARS-CoV-2 molecular test system (Refer to D3005 B), failed to have the appropriate pipettes to dispense volumes less than 10 uL for its molecular SARS-CoV-2 testing (Refer to D3007), failed to establish a competency assessment policy (Refer to D5209), failed to follow its procedure for the performance of SARS-CoV-2 testing using the SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler (Refer to D5401), failed to follow its policy to perform maintenance and function checks for its pipettes used in SARS-CoV-2 testing (Refer to D5433 A), failed perform and document control procedures at least each patient test run for its molecular SARS-CoV-2 test procedure (Refer to D5445), failed to test quality control materials used in its molecular SARS-CoV-2 test system in the

	same manner as patient specimens (Refer to D5465), and failed to ensure SARS-CoV-2 test results generated on the test report were accurate (Refer to D5801).
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 establish a competency assessment policy (Refer to D5209), the laboratory failed to verify the accuracy of its quantitative urine toxicology testing at least semiannually (Refer to D5217), failed to ensure reagents and solutions used in urine toxicology testing were not used beyond their expiration dates (Refer to D5417), and the laboratory failed to follow its policy to perform maintenance and function checks for its pipettes used in quantitative urine toxicology testing (Refer to D5433 A).
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 Laboratory Director, the laboratory failed to establish a competency assessment policy for 2 (December 2020 to December 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's personnel records revealed a lack of competency assessments for the Clinical Consultant and Testing Personnel #1, for the performance of molecular SARS-CoV-2 testing and urine toxicology testing, between August 2021 and December 2022. 2. The surveyor requested the laboratory's established competency assessment policy on 12/21/22 at 12:15 pm and it was not made available. 3. An interview on 12/21/22 at 12:20 pm with the Laboratory Director revealed the laboratory had not established a competency assessment policy.
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 Laboratory Director, the laboratory failed to verify the accuracy of its quantitative urine toxicology testing at least semiannually for 12 of 68 total analytes listed on the laboratory's test menu. Findings include: 1. A review of the laboratory's proficiency testing and verification of accuracy records dated 4/25/22 revealed a document stating, "Split samples sent out to

	ref lab. All results (pos/neg) match 100% 5/1/2022." 2. A review of the quantitative results from the split sample study revealed differences between the laboratory and the reference laboratory results had not been evaluated for its quantitative accuracy. The following analytes had not been evaluated: a. Ritalinic Acid b. Naloxone c. Naltrexone d. Sufentanil e. Norhydrocodone f. Tapentadol g. Hydroxyalprazolam h. Midazolam i. Triazolam j. MDEA k. Methcathinone l. Secobarbital 3. An interview on 12/21/22 at 1:35 pm with the Laboratory Director confirmed the laboratory had not assessed the quantitative results for the 4/25/22 split sample testing event for the analytes listed above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to follow its procedure for the performance of SARS-CoV-2 testing using the SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler for 1 test run observed. Findings include: 1. The surveyor observed the Laboratory Director perform SARS-CoV-2 testing for 5 specimens using its SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler on 12/21/22 at 9:51 am. The Laboratory Director used a Lichen pipette calibrated from 20-200 uL to dispense the following components: a. Dye, 8 uL b. Probes, 10 uL c. Master mix, 15 uL d. Patient sample, 5 uL e. Positive and Negative quality control, 5 uL 2. A review of the laboratory's Lichen Pipette Instructions for Use on 12/21/22 revealed a section stating, "The volume of the pipette is clearly shown through the handle grip window. The delivery volume is set by turning the thumb button clockwise or anticlockwise. When setting the volume, please make sure that: a. the desired delivery volume clicks into place. b. the digits are completely visible in the display window. c the selected volume is within the pipette's specified range." 3. A review of the laboratory's "SeqOnce Biosciences AzureSeq Direct One-Step Universal RT-qPCR Kit SARS-CoV-2 Instructions for Use" on 12/21/22 revealed a section stating, "All instruments must be maintained and operated according to manufacturer's instructions." 4. An interview on 12/21/22 at 9:51 am with the Laboratory Director confirmed the pipette used was not suitable for volumes less than 20 uL.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on a lack of records and interviews with the Laboratory Director, the laboratory failed to establish requirements for specimen transportation for its urine toxicology and SARS-CoV-2 specimens for 2 (December 2020 to December 2022) of 2 years reviewed. Findings include: 1. An interview on 12/21/22 at 12:09 pm with the Laboratory Director revealed the laboratory's specimens used in urine toxicology and SARS-CoV-2 patient testing are received from outside locations. 2. The surveyor requested the laboratory's specimen transportation policy or procedure on 12/21/22 at 12:09 pm and it was not made available. 3. An interview on 12/21/22 at 12:12 pm with the Laboratory Director confirmed the laboratory had not established a specimen transportation procedure for its urine toxicology and SARS-CoV-2 specimens.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Director, the laboratory failed to ensure reagents and solutions used in its urine toxicology testing were labeled to indicate the identity, concentration, and expiration dates of the reagents for 12 of 15 reagents observed in the laboratory. Findings include: 1. The surveyor observed the following containers in the laboratory that did not include the identity, concentration, or expiration dates of the reagents on 12/21/22 at 9:00 am: a. A clear glass container with "MPA 12/8/22" written on it, loaded on the AB Sciex MPX QTrap 4500 analyzer. b. A clear glass container with "IPA 11/30/22" written on it, loaded on the AB Sciex MPX QTrap 4500 analyzer. c. A clear glass container with "MPB 12/8/22" written on it, loaded on the AB Sciex MPX QTrap 4500 analyzer. d. A 1.5 mL microcentrifuge tube labeled with "E" on the lid was in the refrigerator. e. A 1.5 mL microcentrifuge tube labeled with "Int. St." on the lid was in the refrigerator. f. A brown glass container labeled with "IS 11/8" was in the refrigerator. g. A clear glass container with "FA 6/21/21" was on the reagent cart. h. A urine cup with liquid inside and no label. 2. The surveyor observed the following reagents without the concentration and expiration dates on 12/21/22 at 9:00 am: a. A 10 mL plastic conical tube labeled with "Master Mix 12/8/22" was in the refrigerator. b. A clear glass container with "Curve diluent 8/4/2021" was on the reagent cart. c. A plastic squirt bottle labeled with "H2O 12/21" was on the reagent cart. d. A plastic squirt bottle labeled with "MeOH 12/21" was on the reagent cart. 3. An interview on 12/21/22 at 9:

	05 am with the Laboratory Director confirmed the reagents listed above did not have all required elements on the reagent labels.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 the Laboratory Director, the laboratory failed to ensure reagents and solutions used in urine toxicology testing were not used beyond their expiration dates for 3 of 15 reagents observed. Findings include: 1. The surveyor observed the following expired reagents in the laboratory on 12/21/22 at 9: 00 am: a. IMCS reagent rapid hydrolysis buffer, expired 11/2022. b. Acetonitrile, expired 10/22/2020. c. Formic Acid, expired April 2022. 2. An interview on 12/21/22 at 9:10 am with the Laboratory Director confirmed the reagents listed above were expired and had been used in urine toxicology testing beyond their expiration dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to follow its policy to perform maintenance and function checks for its pipettes used in quantitative urine toxicology and SARS-CoV-2 testing for 2 (December 2020 to December 2021) of 2 years reviewed. Findings include: 1. The surveyor toured the laboratory on 12/21/22 at 9:00 am and the following pipettes had been identified: a. Eppendorf Research Plus 1000 uL, calibration sticker 10/8/20 b. Eppendorf 200 uL, calibration sticker 10/8/20 c. Walter 100-1000 uL, sticker stating "New 2/2/2021" d. Walter 10-100 uL, sticker stating "New 2/2/2021" e. Lichen 20-200 uL, sticker stating "New Feb/2/2021" 2. A review of the laboratory's "Pipette Calibration" policy on 12/21/22 revealed a section stating, "After initial verification, pipettes that are designed to deliver a preset volume and/or adjustable volumes must be calibrated annually, when they become contaminated, after major maintenance, and /or when proper operation is in question." 3. An interview on 12/21/22 at 9:51 am with the Laboratory Director revealed the laboratory had not calibrated the pipettes listed above since they had been calibrated initially. B. Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to perform maintenance and function checks for centrifuges used in urine toxicology testing for 2 (December 2020 to December 2022) of 2 years reviewed. Findings include: 1. The surveyor observed a 5430 Eppendorf centrifuge in the laboratory on 12/21/22 at 9:00

	am. 2. A review of the laboratory's "Centrifuge Operation Policy" on 12/21/22 revealed a section stating, "RPM Calibration will be performed annually. The timer will be checked annually or after timer repairs." 3. The surveyor requested documentation of centrifuge annual maintenance from December 2020 to December 2022 on 12/21/22 at 1:52 pm and it was not made available. 4. An interview on 12/21 /22 at 1:52 pm with the Laboratory Director confirmed the laboratory did not perform annual maintenance for the centrifuge according to its policy.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed perform and document control procedures at least each patient test run for its molecular SARS-CoV-2 test procedure for 1 (9/11/21) of 8 patient test runs reviewed. Findings include: 1. A review of 8 patient test runs revealed Patient 9112104 had a test report for SARS-CoV-2 testing with the test report date of 9/11/21. 2. The surveyor requested documentation of the controls performed with the 9/11/21 patient testing run on 12/21/22 at 1:24 pm and they were not made available. 3. A review of the laboratory's "SeqOnce Biosciences AzureSeq Direct One-Step Universal RT-qPCR Kit SARS-CoV-2 Instructions for Use" on 12/21/22 revealed a section stating, "All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted." 4. An interview on 12 /21/22 at 1:24 pm with the Laboratory Director confirmed the laboratory failed to perform and document controls for the 9/11/21 patient test run for SARS-CoV-2.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) 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--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Director, the laboratory failed to test quality control materials used in its molecular SARS-CoV-2 test system in the same manner as patient specimens for 1 test run observed. Findings include: 1. The surveyor observed the Laboratory Director perform SARS-CoV-2 testing for 5 specimens using its SeqOnce Biosciences reagents and the BioRad CFX C1000 thermocycler on 12/21/22 at 9:51 am. The surveyor observed the Laboratory Director add the 5 patient samples into the respective wells before adding the positive and

	negative controls were dispensed. After the positive control was dispensed, the Laboratory Director cleaned his gloved hands and the pipette used to dispense the samples with an ethanol spray before proceeding to dispense the negative control to reduce carryover between the positive control and the negative control. This cleaning was not observed between dispensing patient samples. 2. An interview on 12/21/22 at 1:44 pm with the Laboratory Director confirmed the quality control materials had not been tested in the same manner as the patients were for SARS-CoV-2 testing.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure SARS-CoV-2 test results generated on the test report were accurate for 6 (Patients 09212213, 09212201, 09212215, 09212216, 09212220, and 09212218) of 21 test reports generated on 9/21/22. Findings include: 1. A review of 21 SARS-CoV-2 patient test reports from 9/21/22 revealed the following patient results: a. Patient 09212213 had the result of "NOT DETECTED." b. Patient 09212201 had the result of "DETECTED." c. Patient 09212215 had the result of "DETECTED." d. Patient 09212216 had the result of "DETECTED." e. Patient 09212220 had the result of "NOT DETECTED." f. Patient 09212218 had the result of "NOT DETECTED." 2. A review of the laboratory's "SeqOnce Biosciences AzureSeq Direct COVID-19 Report" from 9/21/22 revealed the same patients listed above had the following result interpretations: a. Patient 09212213 had the result of "DETECTED." b. Patient 09212201 had the result of "NOT DETECTED." c. Patient 09212215 had the result of "NOT DETECTED." d. Patient 09212216 had the result of "NOT DETECTED." e. Patient 09212220 had the result of "DETECTED." f. Patient 09212218 had the result of "DETECTED." 3. An interview on 12/21/22 at 1:54 pm with the Laboratory Director confirmed there had been a discrepancy between the result interpretations and the results on the patient test reports.
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, review of records, and interviews, the Laboratory Director failed to ensure the open-system, molecular SARS-CoV-2 test system utilized by the laboratory could provide quality laboratory services (Refer to D6082 A), failed to

	ensure the urine toxicology testing system could provide quality laboratory services (Refer to D6082 B), failed to ensure the physical conditions of the laboratory were appropriate for the performance of open-system, molecular SARS-CoV-2 testing (Refer to D6083), failed to ensure verification procedures for quantitative urine toxicology testing determined quantitative accuracy (Refer to D6086), failed to ensure testing personnel were performing SARS-CoV-2 testing according to the laboratory's established procedure (Refer to D6087), failed to ensure quality control programs were maintained for its molecular SARS-CoV-2 testing (Refer to D6093), failed to ensure the pipettes used in quantitative urine toxicology and SARS-CoV-2 testing maintained acceptable levels of performance (Refer to D6095), failed to ensure SARS-CoV-2 test results were accurately generated into the final test reports (Refer to D6098), and failed to ensure policies to assess the competency of laboratory personnel were established (Refer to D6103).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with the Laboratory Director, the Laboratory Director failed to ensure the open-system, molecular SARS-CoV-2 test system utilized by the laboratory could provide quality laboratory services. Refer to D3007. B. Based on observation and interview with the Laboratory Director, the Laboratory Director failed to ensure the urine toxicology testing system could provide quality laboratory services. Refer to D5217.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Director, the Laboratory Director failed to ensure the physical conditions of the laboratory were appropriate for the performance of open-system, molecular SARS-CoV-2 testing. Refer to D3005 A and D3005 B.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure verification procedures for quantitative urine toxicology testing determined quantitative accuracy. Refer to D5217.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director, the Laboratory Director failed to ensure testing personnel were performing SARS-CoV-2 testing according to the laboratory's established procedure. Refer to D5401.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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: . Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure quality control programs were maintained for its molecular SARS-CoV-2 testing. Refer to D5445 and D5465.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 observation, record review, and interview with the Laboratory Director, the Laboratory Director failed to ensure the pipettes used in quantitative urine toxicology and SARS-CoV-2 testing maintained acceptable levels of performance. Refer to D5433 A.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure SARS-CoV-2 test results were accurately generated into the final test reports. Refer to D5801.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the Laboratory Director failed to ensure policies to assess the competency of laboratory personnel were established. Refer to D5209.