Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2087522	11/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Lab Houston Lp	9130 South Texas 6, Houston, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5022 - 42 C.F.R. 493.1213 Condition: Toxicology; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
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 review of the laboratory's records and confirmed in interview, it was revealed the laboratory failed to meet the requirements for the subspecialty of toxicology. The findings were: 1. The laboratory failed to have documentation of performing complete preanalytical establishment studies (refer to D5311). 2. The laboratory failed to have documentation of establishing acceptable quality control ranges (refer to D5469). 3. The laboratory failed to include the units of measurement for toxicology patient reports on the Shimadzu 8040 toxicology analyzer (refer to D5805).
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides

	equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and confirmed in interview, it was revealed the laboratory failed to meet pre-analytic system requirements as evidenced by: 1. The laboratory failed to document a stability study that substantiated the conclusions of the Client Service Manual for laboratory-developed tests for urine confirmatory toxicology testing on the Shimadzu 8040 toxicology analyzer. Refer to D5311 2. The laboratory failed to accurately transcribe collection of time of specimens into the laboratory information systems. Refer to D5309.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of the laboratory patient requisitions and final reports and confirmed in interview, the laboratory failed to ensure the laboratory accurately transcribed time of collection of specimens into the laboratory information systems. Findings were: 1. Random review of patient requisitions with the corresponding final reports from August 2018 - October 2018 revealed 10 of 10 patient final reports with the date and time of collection transcribed onto the laboratory information system that did not match the information on the patient requisitions. 47454 date/time of collection on requisition: 8/03/18 1003 hours date/time of collection on final report: 8/03/18 0747 hours 47639 date/time of collection on requisition: 8/29/18 1448 hours date/time of collection on final report: 8/29/18 1030 hours 47705 date/time of collection on requisition: 9/4/18 1719 hours date/time of collection on final report: 9/4/18 0952 hours 47721 date/time of collection on requisition: 9/13/18 0900 hours date/time of collection on final report: 9/13/18 0745 hours 47737 date/time of collection on requisition: 9/12/18 2120 hours date/time of collection on final report: 9/12/18 0950 hours 47849 date/time of collection on requisition: 10/02/18 2000 hours date/time of collection on final report: 10/02/18 0941 hours 47922 date/time of collection on requisition: 10/18/18 1439 hours date/time of collection on final report: 10/18/18 0815 hours 47957 date/time of collection on requisition: 10/19/18 1510 hours date/time of collection on final report: 10/19/18 1009 hours 48006 date/time of collection on requisition: 10/23/18 0900 hours date/time of collection on final report: 10/23/18 0908 hours 47856 date/time of collection on requisition: 10/04/18 1016 hours date/time of collection on final report: 10/04/18 0954 hours 2. An interview with the general supervisor on 11/9/18 at 1010 hours in the office confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, establishment studies, patient final reports, and confirmed in interview, the laboratory failed to document a stability study that substantiated the conclusions of the Client Service Manual for laboratory-developed tests for urine confirmatory toxicology testing on the Shimadzu 8040 toxicology analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory performed toxicology testing on the Shimadzu 8040 toxicology analyzer for the following 69 analytes. lorazepam Fluoxetine Norpropoxyphene Venlafaxine O-Desmethylvenlafaxine Levetiracetam Cyclobenzaprine Chlordiazepoxide Clomipramine Desmethylclomipramine Traxodone Zaleplon Zolpidem Zopiclone Norfluoxetine Nortriptyline Peroxetine Pentazocine Phenobarbital Pregabalin 6-Acetylmorphine 7-Aminoclonazepam Alprazolam Amphetamine aOH-Alprazolam Benzolecgonine Buprenorphine Carisoprodol Codeine EDDP Fentanyl Hydrocodone Hydromorphone MDMA Meperidine Meprobamate Methadone Methamphetamine Morphine Norbuprenorphine Nordiazepam Norfentanyl Norhydrocodone Normeperidine Noroxycodone O-demethyltramadol Oxazepam oxycodone Oxymorphone PCP Propoxyphene Tapentadol Temazepam THC-COOH Tramadol Amitriptyline Butalbital Citalopram Desipramine Desmethylcitalopram Desmethyldoxepin Doxepin Gabapentin Imipramine Ritalinic Acid Sertraline MDPV Mitagynine Naloxone 2. Review of the laboratory Specimen Submission, Handling and Referral under specimen storage and preservative revealed "refrigerate for three days or freeze indefinitely." 3. Review of the laboratory stability studies available revealed the laboratory performed refrigerated storage stability for 13 of 69 analytes at day 1 and day 7. Norpropoxyphene Chlordiazepoxide Clomipramine Cyclobenzaprine Levetiracetam O-desmethylvenlafaxine Traxodone Venlafaxine Zalepon Zolpidem Zopiclone Desmethylclomipramine Norchlordiazepoxide 4. Review of the refrigerated storage stability revealed no documentation of the Day 2 or Day 3 for the above 13 of 69 analytes. 5. Review of the refrigerated storage stability revealed no documentation of the refrigerated stability for 56 of 69 analytes. lorazepam Fluoxetine Ritalinic Acid Norfluoxetine Nortriptyline Peroxetine Pentazocine Phenobarbital Pregabalin 6-Acetylmorphine 7-Aminoclonazepam Alprazolam Amphetamine aOH-Alprazolam Benzolecgonine Buprenorphine Carisoprodol Codeine EDDP Fentanyl Hydrocodone Hydromorphone MDMA Meperidine Meprobamate Methadone Methamphetamine Morphine Norbuprenorphine Nordiazepam Norfentanyl Norhydrocodone Normeperidine Noroxycodone O-demethyltramadol Oxazepam oxycodone Oxymorphone PCP Propoxyphene Tapentadol Temazepam THC-COOH Tramadol Amitriptyline Butalbital Citalopram Desipramine Desmethylcitalopram Desmethyldoxepin Doxepin Gabapentin Imipramine Ritalinic Acid Sertraline MDPV Mitagynine Naloxone 6. Random review of the laboratory patient final reports from August to October 2018 revealed the laboratory performed urine confirmatory testing with an elapsed time greater than 3 days: Accn # 47638: collection date 08/30/2018; run date: 09/07/2018, elapsed time 8 days 47639: collection date 08/29/2019; run date: 09/07/2019, elapsed time 9 days 47642: collection date 08/30/2018; run date: 09/07/2018, elapsed time 8 days 47667: collection date 09/05/2018; run date 09/13/2018, elapsed time 8 days 47668: collection date 09/04/2018; run date 09/13/2018, elapsed time 9 days 47745: collection date 09/17/2018; run date 09/28/2018, elapsed time 11 days 47739: collection date 09/15/2018; run date 09/25/2018, elapsed time 10 days 47752: collection date 09/19/2018; run date 09/28/2018, elapsed time 9 days

	47774: collection date 09/27/2018; run date 10/08/2018, elapsed time 11 days 47781: collection date 09/25/2018; run date10/08/2018, elapsed time 13 days 7. An interview with the general supervisor on 11/8/18 at 1030 hours in the office confirmed the above findings. He was unaware the laboratory needed to perform stability testing for each day the laboratory received specimen.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and confirmed in interview, the laboratory failed to have written instructions available to the laboratory's clients that included information on specimen conditions for transportation. Findings included: 1. Review of laboratory policy Specimen Submission, Handling, and Referral (approved 10/17/14) revealed no documentation of the "refrigerated," "frozen," or "room temperature" acceptable temperature range. 2. An interview with the general supervisor on 11/8/18 at 1030 hours in the office confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on laboratory records, observations, review of the laboratory establishment studies, laboratory quality control records and patient logs, and confirmed in interview, the laboratory failed to document complete establishment studies for the standards and stock solutions used for the laboratory-developed tests for urine toxicology confirmatory testing on the Shimadzu 8040 toxicology analyzer. Findings were: 1. Review of the the laboratory worksheet used to prepare stock solutions revealed "stable up to 6 months when stored @ -20C." 2. A tour of the laboratory on 11/8/18 at 1310 hours revealed standards and stock solutions stored frozen in the laboratory freezer. IS [internal standard] Stock lot 07272018 (in use: 08/09/18, exp 1 /27/19) Reagent Standard stock lot # MAS06222018 (prep 6/22/18, exp 12/22/18, in use 7/5/18) Reagent Standard stock lot # MAS 09102018 (prep 9/10/18, exp 3/10/19, in use 10/5/18) 3. Review of the laboratory establishment studies revealed no documentation of the stability studies for the above standards and stock solutions. 4. Random review of the August - October 2018 toxicology patient log sheets and

	quality control records revealed the laboratory performed patient testing using the above standards and stock solutions. Date accession # 08/29/18 47639 08/03/18 47454 09/12/18 47717 09/04/18 47705 09/13/18 47721 09/12/18 47737 10/24/18 48007 10 /02/18 47849 5. An interview with the general supervisor on 11/8/18 at 1400 hours in the office confirmed the above findings. He was unaware the laboratory was required to perform the stability studies for the reagent stocks and standards.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory quality control records, laboratory patient records, and confirmed in interview, the laboratory failed to establish the quality control (QC) acceptable range for the Shimadzu 8040 toxicology analyzer . Findings were: 1. Review of the package insert for the Affirm DAU 1 & 2 (catalog number: IR960 DAU, kit lot 1003e) revealed "laboratories should establish their own statistical values for precision and expected range." 2. Review of the package insert for the DAU HC2 Urine Toxicology control (Product Number 50701) revealed "laboratories should establish their own statistical values for precision and expected range." 3. Review of the package insert for the Benzodiazepines Plus 400 ng /mL urine Toxicology Control (Product Number 12091) revealed "laboratories should establish their own statistical values for precision and expected ranges; these values should fall within +/- 15% of the target value." 4. Review of the laboratory 2018 toxicology records revealed the laboratory performed toxicology testing on the Shimadzu 8040 toxicology analyzer for the following 65 analytes used the corresponding target value +/- 20% for the Affirm DAU 1 & 2 quality control material. DAU-1 low control (lot#131807e, exp 7/13/19) Lorazepam (acceptable range: 256 - 384 ng/mL) Fluoxetine (acceptable range: 320 - 480 ng/mL) Norpropoxyphene (acceptable range: 320 - 480 ng/mL) Butalbital (acceptable range: 640 - 960 ng/mL) Venlafaxine (acceptable range: 320 - 480 ng/mL) O-Desmethylvenlafaxine (acceptable range: 64 - 96 ng/mL) Levetiracetam (acceptable range: 320 - 480 ng/mL) Cyclobenzaprine (acceptable range: 320 - 480 ng/mL) Codeine (acceptable range: 320 - 480 ng/mL) Clomipramine (acceptable range: 320 - 480 ng/mL) Desmethylclomipramine (acceptable range: 320 - 480 ng/mL) Traxodone (acceptable range: 320 - 480 ng/mL) Zaleplon (acceptable range: 32 - 48 ng/mL) Zolpidem (acceptable range: 320 - 480 ng/mL) Norfluoxetine (acceptable range: 320 - 480 ng/mL) Nortriptyline (acceptable range: 320 - 480 ng/mL) Peroxetine (acceptable range: 320 - 480 ng/mL) Pentazocine (acceptable range: 96 - 144 ng/mL) Phenobarbital (acceptable range: 640 - 960 ng/mL) Pregabalin (acceptable range: 960

- 1440 ng/mL) 6-Acetylmorphine (acceptable range: 10 - 15 ng/mL) 7-Aminoclonazepam (acceptable range: 256 - 384 ng/mL) Alprazolam (acceptable range: 256 - 384 ng/mL) Amphetamine (acceptable range: 320 - 480 ng/mL) aOH-Alprazolam (acceptable range: 256 - 384 ng/mL) Benzolecgonine (acceptable range: 160 - 240 ng/mL) Buprenorphine (acceptable range: 32 - 48 ng/mL) Carisoprodol (acceptable range: 320 - 480 ng/mL) EDDP (acceptable range: 320 - 480 ng/mL) Fentanyl (acceptable range: 32 - 48 ng/mL) Hydrocodone (acceptable range: 320 - 480 ng/mL) Hydromorphone (acceptable range: 320 - 480 ng/mL) MDMA (acceptable range: 320 - 480 ng/mL) Meperidine (acceptable range: 160 - 240 ng/mL) Meprobamate (acceptable range: 320 - 480 ng/mL) Methadone (acceptable range: 320 - 480 ng/mL) Methamphetamine (acceptable range: 320 - 480 ng/mL) Morphine (acceptable range: 320 - 480 ng/mL) Norbuprenorphine (acceptable range: 160 - 240 ng/mL) Nordiazepam (acceptable range: 256 - 384 ng/mL) Norfentanyl (acceptable range: 26 - 38 ng/mL) Norhydrocodone (acceptable range: 320 - 480 ng/mL) Normeperidine (acceptable range: 160 - 240 ng/mL) Noroxycodone (acceptable range: 160 - 240 ng/mL) O-demethyltramadol (acceptable range: 320 - 480 ng/mL) Oxazepam (acceptable range: 256 - 384 ng/mL) oxycodone (acceptable range: 160 - 240 ng/mL) Oxymorphone (acceptable range: 320 - 480 ng/mL) PCP (acceptable range: 32 - 48 ng/mL) Propoxyphene (acceptable range: 320 - 480 ng/mL) Tapentadol (acceptable range: 160 - 240 ng/mL) Temazepam (acceptable range: 256 - 384 ng/mL) THC-COOH (acceptable range: 192 - 288 ng/mL) Tramadol (acceptable range: 320 - 480 ng/mL) Amitriptyline (acceptable range: 320 - 480 ng/mL) Citalopram (acceptable range: 320 - 480 ng/mL) Desipramine (acceptable range: 320 - 480 ng /mL) Desmethylcitalopram (acceptable range: 320 - 480 ng/mL) Desmethyldoxepin (acceptable range: 320 - 480 ng/mL) Doxepin (acceptable range: 320 - 480 ng/mL) Gabapentin (acceptable range: 960 - 1440 ng/mL) Imipramine (acceptable range: 320 - 480 ng/mL) Ritalinic Acid (acceptable range: 320 - 480 ng/mL) Sertraline (acceptable range: 320 - 480 ng/mL) MDPV (acceptable range: 320 - 480 ng/mL) Mitragynine (acceptable range: 64 - 96 ng/mL) Naloxone (acceptable range: 320 - 480 ng/mL) DAU-2 high control (lot#131807e, exp 7/13/19) lorazepam (acceptable range: 2560 - 3840 ng/mL) Fluoxetine (acceptable range: 3200 - 4800 ng/mL) Norpropoxyphene (acceptable range: 3200 - 4800 ng/mL) Venlafaxine (acceptable range: 3200 - 4800 ng/mL) Butalbital (acceptable range: 6400 - 9600 ng/mL) O-Desmethylvenlafaxine (acceptable range: 640 - 960 ng/mL) Levetiracetam (acceptable range: 3200 - 4800 ng/mL) Cyclobenzaprine (acceptable range: 3200 - 4800 ng/mL) Clomipramine (acceptable range: 3200 - 4800 ng/mL) Desmethylclomipramine (acceptable range: 3200 - 4800 ng/mL) Traxodone (acceptable range: 3200 - 4800 ng /mL) Zaleplon (acceptable range: 320 - 480 ng/mL) Zolpidem (acceptable range: 3200 - 4800 ng/mL) Norfluoxetine (acceptable range: 2560 - 3840 ng/mL) Nortriptyline (acceptable range: 2560 - 3840 ng/mL) Peroxetine (acceptable range: 2560 - 3840 ng /mL) Pentazocine (acceptable range: 960 - 1440 ng/mL) Phenobarbital (acceptable range: 6400 - 9600 ng/mL) Pregabalin (acceptable range: 9600 - 14400 ng/mL 6-Acetylmorphine (acceptable range: 256 - 384 ng/mL) 7-Aminoclonazepam (acceptable range: 2560 - 3840 ng/mL) Alprazolam (acceptable range: 2560 - 3840 ng /mL) Amphetamine (acceptable range: 3200 - 4800 ng/mL) aOH-Alprazolam (acceptable range: 2560 - 3840 ng/mL) Benzolecgonine (acceptable range: 1600 - 2400 ng/mL) Buprenorphine (acceptable range: 320 - 480 ng/mL) Carisoprodol (acceptable range: 3200 - 4800 ng/mL) Codeine (acceptable range: 3200 - 4800 ng /mL) EDDP (acceptable range: 3200 - 4800 ng/mL) Fentanyl (acceptable range: 256 - 384 ng/mL) Hydrocodone (acceptable range: 3200 - 4800 ng/mL) Hydromorphone (acceptable range: 3200 - 4800 ng/mL) MDMA (acceptable range: 3200 - 4800 ng /mL) Meperidine (acceptable range: 1600 - 2400 ng/mL) Meprobamate (acceptable range: 3200 - 4800 ng/mL) Methadone (acceptable range: 3200 - 4800 ng/mL)

	Methamphetamine (acceptable range: 3200 - 4800 ng/mL) Morphine (acceptable range: 3200 - 4800 ng/mL) Norbuprenorphine (acceptable range: 1600 - 2400 ng/mL) Nordiazepam (acceptable range: 2560 - 3840 ng/mL) Norfentanyl (acceptable range: 256 - 384 ng/mL) Norhydrocodone (acceptable range: 3200 - 4800 ng/mL) Normeperidine (acceptable range: 1600 - 2400 ng/mL) Noroxycodone (acceptable range: 1600 - 2400 ng/mL) O-demethyltramadol (acceptable range: 640 - 960 ng/mL) Oxazepam (acceptable range: 2560 - 3840 ng/mL) oxycodone (acceptable range: 1600 - 2400 ng/mL) Oxymorphone (acceptable range: 3200 - 4800 ng/mL) PCP (acceptable range: 320 - 480 ng/mL) Propoxyphene (acceptable range: 3200 - 4800 ng/mL) Tapentadol (acceptable range: 1600 - 2400 ng/mL) Temazepam (acceptable range: 2560 - 3840 ng/mL) THC-COOH (acceptable range: 1920 - 2880 ng/mL) Tramadol (acceptable range: 3200 - 4800 ng/mL) Amitriptyline (acceptable range: 3200 - 4800 ng/mL) Citalopram (acceptable range: 3200 - 4800 ng/mL) Desipramine (acceptable range: 3200 - 4800 ng/mL) Desmethylcitalopram (acceptable range: 3200 - 4800 ng /mL) Desmethyldoxepin (acceptable range: 3200 - 4800 ng/mL) Doxepin (acceptable range: 3200 - 4800 ng/mL) Gabapentin (acceptable range: 9600 - 14400 ng/mL) Imipramine (acceptable range: 3200 - 4800 ng/mL) Ritalinic Acid (acceptable range: 3200 - 4800 ng/mL) Sertraline (acceptable range: 3200 - 4800 ng/mL) MDPV (acceptable range: 3200 - 4800 ng/mL) Mitragynine (acceptable range: 640 - 960 ng /mL) Naloxone (acceptable range: 3200 - 4800 ng/mL) 5. Review of the laboratory 2018 toxicology records revealed the laboratory performed toxicology testing on the Shimadzu 8040 toxicology analyzer for the following 18 analytes used the corresponding target value +/- 20% for the DAU HC 2 Urine Toxicology control. 6-MAM (acceptable range: 400 - 600 ng/mL) Amphetamine (acceptable range: 400 - 600 ng/mL) aOH-Alprazolam (acceptable range: 240 - 360 ng/mL) Benzoylecgonine (acceptable range: 120 - 180 ng/mL) Butalbital (acceptable range: 240 - 360 ng/mL) Codeine (acceptable range: 1600 - 2400 ng/mL) EDDP (acceptable range: 240 - 360 ng/mL) Loracepam (acceptable range: 240 - 360 ng/mL) MDMA (acceptable range: 400 600 ng/mL) Methadone (acceptable range: 240 - 360 ng/mL) Methamphetamine (acceptable range: 400 - 600 ng/mL) Morphine (acceptable range: 1600 - 2400 ng /mL) Nordiazepam (acceptable range: 240 - 360 ng/mL) Nortriptyline (acceptable range: 240 - 360 ng/mL) Oxazepam (acceptable range: 240 - 360 ng/mL) PCP (acceptable range: 20 - 30 ng/mL) Phenobarbital (acceptable range: 240 - 360 ng/mL) Temazepam (acceptable range: 240 - 360 ng/mL) 6. Review of the laboratory 2018 toxicology records revealed the laboratory performed toxicology testing on the Shimadzu 8040 toxicology analyzer for the analyte Norchlordiazepoxide using the corresponding target value +/- 20% for the Benzodiazepines Plus 400 ng/mL Urine toxicology Control. Benzodiazepine (lot # A8684, exp 03/20) Norchlordiazepoxide (acceptable range: 320 - 480 ng/mL) 7. Review of the laboratory records available revealed no documentation of the laboratory establishing its own acceptable range for the above quality controls. 8. Random review of the laboratory patient records from August 2018 to October 2018 revealed the laboratory performed patient testing on days when the laboratory used the above quality controls. Date accession # 08/29/18 47639 08/03/18 47454 09/12/18 47717 09/04/18 47705 09/13/18 47721 09/12/18 47737 10/24/18 48007 10/02/18 47849 9. An interview with the general supervisor on 11/8/18 at 1505 hours in the office confirmed the above findings. He was unaware the laboratory should establish its own acceptable quality control ranges.
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 review of the laboratory establishment records, patient final reports, and confirmed in interview, the laboratory failed to have an adequate system in place to ensure the accuracy and reliability of data sent to the Laboratory Information System (LIS) from the Shimadzu 8040 toxicology analyzer Findings include: 1. Review of the Shimadzu 8040 establishment studies revealed the limit of detection and/or limit of quantitation for the following analytes: Fluoxitine limit of detection 65.23 ng/mL Morphine limit of quantitation 5208 ng/mL Norfentanyl limit of quantitation 410 ng /mL 2. Random review of patient final reports from August 2018 to October 2018 revealed 6 of 11 patient reports with values documented outside of the limit of detection and/or limit of quantitation for the above analytes. 08/29/18: 47636, Fluoxitine 0 08/03/18: 47454, Fluoxitine 23 09/04/18: 47705, Fluoxitine 25 09/12/18: 47737, Morphine 23801 10/24/18: 48807, Morphine 14518 10/02/18: 47849, Norfentanyl 2816 3. An interview with the general supervisor on 11/8/18 at 1450 hours in the office confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(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: A. Based on a review of patient test reports and interview of facility personnel, it was revealed that the laboratory failed to include a disclaimer on test reports for the laboratory developed tests on the Shimadzu 8040 toxicology analyzer testing not FDA- cleared. Findings were: 1. A review of the FDA (Federal Drug Administration) website revealed the Shimadzu 8040 analyzer was not listed on the FDA website. Tests on the Shimadzu 8040 analyzer are non-FDA approved, therefore the complexity is high and is a Laboratory Developed Test. 2. Review of test reports revealed the laboratory tested for the following 69 drug analytes on the Shimadzu 8040 analyzer : lorazepam Fluoxetine Norpropoxyphene Venlafaxine O-Desmethylvenlafaxine Levetiracetam Cyclobenzaprine Chlordiazepoxide Clomipramine Desmethylclomipramine Traxodone Zaleplon Zolpidem Zopiclone Norfluoxetine Nortriptyline Peroxetine Pentazocine Phenobarbital Pregabalin 6-Acetylmorphine 7-Aminoclonazepam Alprazolam Amphetamine aOH-Alprazolam Benzolecgonine Buprenorphine Carisoprodol Codeine EDDP Fentanyl Hydrocodone Hydromorphone MDMA Meperidine Meprobamate Methadone Methamphetamine

	Morphine Norbuprenorphine Nordiazepam Norfentanyl Norhydrocodone Normeperidine Noroxycodone O-demethyltramadol Oxazepam oxycodone Oxymorphone PCP Propoxyphene Tapentadol Temazepam THC-COOH Tramadol Amitriptyline Butalbital Citalopram Desipramine Desmethylcitalopram Desmethyldoxepin Doxepin Gabapentin Imipramine Ritalinic Acid Sertraline MDPV Mitagynine Naloxone 3. Random review of 8 patient final reports from August 2018 to October 2018 revealed 8 of 8 test reports did not include the statement "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration". Date accession # 08/29/18 47639 08/03/18 47454 09/12/18 47717 09/04/18 47705 09/13/18 47721 09/12/18 47737 10/24/18 48007 10/02/18 47849 4. An interview with the general supervisor on 11/9/18 at 1000 hours in the office confirmed the above findings. He acknowledged that the lab reports did not include the required verbiage. B. Based on review of the laboratory patient test reports and confirmed in interview, the laboratory failed to include the units of measurement for 8 of 8 toxicology patient reports on the Shimadzu 8040 toxicology analyzer. Findings were: 1. Random review of 8 patient final reports from August 2018 to October 2018 revealed 8 of 8 test reports did not include the units of measurement for 69 of the 69 analytes performed on the Shimadzu 8040 toxicology analyzer Date accession # 08/29/18 47639 08/03/18 47454 09/12/18 47717 09/04/18 47705 09/13/18 47721 09/12/18 47737 10/24/18 48007 10/02/18 47849 2. An interview with the general supervisor on 11/9/18 at 1000 hours in the office confirmed the above findings. He acknowledged that the lab reports did not include the units of measurement.
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. (Refer to D6082, D6086, D6093)
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: Based on a review of laboratory preanalytic systems and analytic systems, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provided quality laboratory services for all aspects of test performance. (refer to D5311, D5469, D5805)
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 a review of the laboratory's test system records and interview of facility personnel, the laboratory director failed to ensure the laboratory documented complete establishment of standards, calibrators, and stock solutions for its test systems before reporting patient test results. (Refer to D5423)
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 review of quality control records and interview, the laboratory director failed to ensure that the quality control programs were established to identify failures in quality as they occurred. Please see D5469.