Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2074140	10/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Affiliates Of Northeast Hou, Llc	22001 Northpark Dr Suite 221, Kingwood, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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: Based on observation and interview, the laboratory failed to establish a uni-directional workflow for the molecular amplification that included a separate area for specimen preparation and reagent preparation for PGX (pharmacogenomics) patient testing on the Applied Biosystems Quant Studio 12k Flex analyzer. Findings were: 1. Surveyor observations on 10/11/18 at 1020 hours revealed the testing person prepared reagents and specimen in the same area in the PGX amplification room. 2. An interview with the general supervisor on 10/11/18 at 1040 hours in the laboratory confirmed the above findings. He was unaware that the reagent preparation and sample preparation need to be in separate areas.
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 review of the 2016 and 2017 personnel records, laboratory policies, and confirmed in interview, the laboratory failed to document the competency assessment for 1 of 1 general supervisor (GS) and 2 of 2 technical supervisors (TS). Findings were: 1. Review of the 2016 and 2017 personnel records revealed no documentation of the competency assessments for 1 of 1 general supervisor (hire date 12/2016) and 2 of 2 technical supervisors (TS #1 hire date 12/2016, TS#2 hire date 05/2017). 2. An interview with the general supervisor on 10/11/18 at 1420 hours confirmed the above findings. He was unaware the GS and TS required competencies.
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 a review of College of American Pathologists (CAP) proficiency testing records from 2016 and 2017 and confirmed in interview, the laboratory failed to verify twice annually the accuracy of all tests it performed on the API-3000 LC/MS /MS analyzer. The findings were: 1. The laboratory's test menu included a total of 76 toxicology tests performed on the API-3000 LC/MS/MS analyzer: 6-Monoacetylmorphine (6-MAM) 11-Nor-9-carboxy -tetrahydrocannabinol (11-COOH-THC or THC-COOH) 7 Amino-clonazepam Alpha-hydroxyalprazolam Alprazolam Amitripyline Amphetamine Benzolecgonine Buprenorphine Butalbital Carisoprodol Citalopram Clomipramine Codeine Cotinine Cyclobenzaprine Desipramine Desalkylflurazepam Dextromethorphan Doxepin Duloxetine EDDP ETS ETG Fentanyl Fluoxetine Gabapentine Hydrocodone Hydromorphone Hydroxymidazolam Imapramine Ketamine Lorazepam MDA MDMA MDPV Meperidine Meprobamate Mephedrone Methadone Methylone Methamphetamine Mitraginine Morphine N-Desmethyl-Tapentadol Naloxone Naltrexone Norbuprenorphine Nordiazepam Norfentanyl Norfluoxetine Norketamine Nortripyline Noroxycodone Norhydrocodone Normeperidine o-desmethyltramadol o-desmethylvenlafaxine Oxazepam Oxycodone Oxymorphone Paroxetine Phenobarbital Phencyclidine Phentermine Pregabalin Ritalinic acid Sertraline Secobarbital Sufantanil Tapentadol Tramadol Temazepam Trimipramine Venlafaxine Zolpidam-4-Carboxylic Acid 2. Review of the 2016 proficiency testing records revealed no documentation of twice annual assessment for 18 of 76 analytes on the API-3000 LC/MS/MS analyzer Codeine, Tramadol, Tapentadol, Alprazolam, aOH-Alprazolam, Carisoprodol, Meprobamate, PCP Hydrocodone Hydromorphone Fentanyl Methadone EDDP Nordiazepam Benzolecogine 6-MAM Methamphetamine THC-COOH 3. Review of the 2017 proficiency testing records revealed no documentation of twice annual assessment for 18 of 76 analytes on the API-3000 LC/MS/MS analyzer Codeine, Tramadol, Tapentadol, Alprazolam, aOH-Alprazolam, Carisoprodol, Meprobamate, PCP Hydrocodone Hydromorphone Fentanyl Methadone EDDP Nordiazepam Benzolecogine 6-MAM Methamphetamine THC-COOH 4. An interview with the primary testing person on 10/10/18 at 1100 hours in the laboratory confirmed the above findings. He stated that he had trouble finding another laboratory to perform the accuracy assessment for the missing analytes.

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 API-3000 LC/MS/MS toxicology analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory performed toxicology testing on the API-3000 LC/MS/MS toxicology analyzer for the following analytes. 6-Monoacetylmorphine (6-MAM) 11-Nor-9-carboxy -tetrahydrocannabinol (11-COOH-THC or THC-COOH) 7 Amino-clonazepam Alpha-hydroxyalprazolam Alprazolam Amitripyline Amphetamine Benzolecgonine Buprenorphine Butalbital Carisoprodol Citalopram Clomipramine Codeine Cotinine Cyclobenzaprine Desipramine Desalkylflurazepam Dextromethorphan Doxepin Duloxetine EDDP ETS ETG Fentanyl Fluoxetine Gabapentine Hydrocodone Hydromorphone Hydroxymidazolam Imapramine Ketamine Lorazepam MDA MDMA MDPV Meperidine Meprobamate Mephedrone Methadone Methylone Methamphetamine Mitraginine Morphine N-Desmethyl-Tapentadol Naloxone Naltrexone Norbuprenorphine Nordiazepam Norfentanyl Norfluoxetine Norketamine Nortripyline Noroxycodone Norhydrocodone Normeperidine o-desmethyltramadol o-desmethylvenlafaxine Oxazepam Oxycodone Oxymorphone Paroxetine Phenobarbital Phencyclidine Phentermine Pregabalin Ritalinic acid Sertraline Secobarbital Sufantanil Tapentadol Tramadol Temazepam Trimipramine Venlafaxine Zolpidam-4-Carboxylic Acid 2. Review of the laboratory manual BAS Premier Lab Client Service Manual (Toxicology) revealed "specimens should be sent on the same day of collection. Specimens are stable at room temperature up to 12 days." 3. Review of the laboratory establishment studies revealed documentation the laboratory performed room temperature (18-25C) stability for 76 of 76 analytes at Day 0, Day 1, Day 3, Day 5, Day 7, Day 9, Day 12, and Day 15. 4. Further review of the room temperature stability study revealed no documentation of the stability for 76 of 76 analytes for Day 2, Day 4, Day 8, Day 10, Day 11, Day 13, and Day 14. Note: Review of the laboratory CMS116 revealed the laboratory hours of operation was Monday to Friday 9 am to 5 pm. 5. Random review of July to September 2018 laboratory records revealed the laboratory performed toxicology patient testing with elapsed time of Day 2, Day 4, and Day 6. 7/23/18 Patient accession TOX000007716; collected 7/19/18; received 7/23/18; elapsed time 4 days 8/6/18 Patient accession TOX000008176; collected 7/31/18; received 8/06/18; elapsed time 6 days 8/6/18 Patient accession TOX000008181; collected 7/31/18; received 8/06/18; elapsed time 6 days 8/13/18 Patient accession TOX000008405; collected 08/09/18; received 8/13/18; elapsed time 4 days 9/11/18 Patient accession TOX000009299; collected 09/07/18; received 09/11/18; elapsed time 2 days 6. An interview with the general supervisor on 10/10/18 at 1215 hours in the laboratory confirmed the above findings. He was unaware the laboratory was required to perform stability studies for each day.

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 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 calibrations, controls, and internal standards working solutions used for the laboratory-developed tests for urine toxicology confirmatory testing on the API-3000 LC/MS/MS toxicology analyzer. Findings were: 1. A tour of the laboratory on 10/10/18 at 1100 hours revealed the following 6 standards, controls, and internal standards working solutions stored in the Tox laboratory freezer (-20 C). Method 2 IS [internal standard] working solution prepared 7/18/18 expiration 10/18/18 Method 1/3 IS working solution prepared 9/18 /18 expiration 3/18/19 Method 2 QC [quality control] stock prepared 06/04/18 expiration 06/04/19 Method 2 Cal [calibrators] stock prepared 8/4/18 expiration 6/4 /19 Method 1/3 QC stock prepared 6/4/18 expiration 6/4/19 Method 1/3 Cal stock prepared 6/4/18 expiration 6/4/19 2. Review of the laboratory establishment studies revealed no documentation of stability studies for the above standards, controls, and internal standard working solutions. 3. Random review of the July to September 2018 toxicology patient log sheets and quality control records revealed the laboratory performed patient testing using the above calibrations, controls, and internal standards working solutions. 7/23/18 Patient accession TOX000007695 7/23/18 Patient accession TOX000007716 8/3/18 Patient accession TOX000008143 8/6/18 Patient accession TOX000008176 8/6/18 Patient accession TOX000008181 8/10/18 Patient accession TOX000008357 8/13/18 Patient accession TOX000008405 9/11/18 Patient accession TOX000009299 9/28/18 Patient accession TOX000009828 4. An interview with testing person #1 on 10/10/18 at 1115 hours in the laboratory confirmed the above findings. She stated that she prepared calibrators, standards and controls every few months but was unaware stability studies were required for them.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory extraction worksheets, and confirmed in interview, the laboratory failed to perform two control materials during the extraction phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quant Studio 12k Flex. Findings were: 1. Surveyor observations on 10/11/18 at 1020 hours in the PGX extraction room revealed the general supervisor failed to perform 2 external quality controls for during extraction of PGX testing. He only performed 1 of 2 external quality control (NTC- no template control). 2. Random review of the laboratory extraction worksheets from June to October 2018 revealed 3 of 3 days when the laboratory had documentation of 1 of 2 extraction control (NTC) for the following days of patient testing. 6/30/18 7/2/18 10/11/18 3. Random review of laboratory patient records of the above dates revealed the laboratory performed patient testing on the above dates. 6/30/18 Patient ID GEN000001988 7/2/18 Patient ID GEN000001980 10/11/18 Patient ID GEN000002348 Patient ID GEN000002338 Patient ID GEN000002350 Patient ID GEN000002351 4. An interview with the general supervisor on 10/11/18 at 1120 hours in the laboratory confirmed the above findings. He was unaware he needed to perform 2 extraction controls every day of patient testing. According to the CMS-116 signed by the laboratory director on 10/2 /18, the facility performed 79860 PGX testing annually.
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 API-3000 LC/MS/MS toxicology analyzer. Findings were: 1. Review of the laboratory quality control (QC) toxicology records from June to September 2018 revealed the laboratory performed quality control toxicology testing on the API-3000 LC/MS/MS toxicology analyzer for the following 76 analytes using the analyte target range +/- 25 %. Method 2 QC [quality control] stock prepared 06/04/18 expiration 06/04/19 Method 1/3 QC stock prepared 6/4/18 expiration 6/4/19 6-Monoacetylmorphine (6-MAM) (Low: 12.8 - 19.2 ng/mL; Mid: 64 - 96 ng/mL; High 320 - 480 ng/mL) THC-COOH (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) 7 Amino-clonazepam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Alpha-hydroxyalprazolam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng /mL) Alprazolam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng /mL) Amitripyline (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng

/mL) Amphetamine (Low: 64 - 96 ng/mL; Mid: 320 - 480 ng/mL; High 1600 - 2400 ng/mL) Benzolecgonine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Buprenorphine (Low: 9.4 - 9.6 ng/mL; Mid: 32 - 48 ng/mL; High: 160 - 240 ng/mL) Butalbital (Low: 128 - 192 ng/mL; Mid: 640 - 960 ng/mL; High 3200 - 4800 ng/mL) Carisoprodol (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Citalopram (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Clomipramine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Codeine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Cotinine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng /mL) Cyclobenzaprine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Desipramine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Desalkylflurazepam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Dextromethorphan (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Doxepin (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Duloxetine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) EDDP (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng /mL) ETS (Low: 128 - 192 ng/mL; Mid: 640 - 960 ng/mL; High 3200 - 4800 ng/mL) ETG (Low: 320 - 480 ng/mL; Mid: 1600 - 2400 ng/mL; High 8000 - 12000 ng/mL) Fentanyl (Low: 9.4 - 9.6 ng/mL; Mid: 32 - 48 ng/mL; High: 160 - 240 ng/mL) Fluoxetine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Gabapentine (Low: 128 - 192 ng/mL; Mid: 640 - 960 ng/mL; High 3200 - 4800 ng /mL) Hydrocodone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng /mL) Hydromorphone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Hydroxymidazolam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Imapramine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Ketamine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Lorazepam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) MDA (Low: 64 - 96 ng/mL; Mid: 320 - 480 ng/mL; High 1600 - 2400 ng /mL) MDMA (Low: 64 - 96 ng/mL; Mid: 320 - 480 ng/mL; High 1600 - 2400 ng/mL) MDPV (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Meperidine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Meprobamate (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Mephedrone (Low: 32 - 48 ng/m(Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Methadone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Methylone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Methamphetamine (Low: 64 - 96 ng/mL; Mid: 320 - 480 ng/mL; High 1600 - 2400 ng/mL) Mitraginine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Morphine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) N-Desmethyl-Tapentadol (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Naloxone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Naltrexone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng /mL; High: 800 - 1200 ng/mL) Norbuprenorphine (Low: 12.8 - 19.2 ng/mL; Mid: 64 - 96 ng/mL; High 320 - 480 ng/mL) Nordiazepam (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Norfentanyl (Low: 9.4 - 9.6 ng/mL; Mid: 32 - 48 ng /mL; High: 160 - 240 ng/mL) Norfluoxetine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng /mL; High: 800 - 1200 ng/mL) Norketamine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng /mL; High: 800 - 1200 ng/mL) Nortripyline (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng /mL; High: 800 - 1200 ng/mL) Noroxycodone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Norhydrocodone (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Normeperidine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) o-desmethyltramadol (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) o-desmethylvenlafaxine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Oxazepam (Low: 32 - 48

	ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Oxycodone (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Oxymorphone (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Paroxetine (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Phenobarbital (Low: 128 - 192 ng/mL; Mid: 640 - 960 ng/mL; High 3200 - 4800 ng/mL) Phencyclidine (Low: 9.4 - 9.6 ng/mL; Mid: 32 - 48 ng/mL; High: 160 - 240 ng/mL) Phentermine (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Pregabalin (Low: 128 - 192 ng/mL; Mid: 640 - 960 ng/mL; High 3200 - 4800 ng/mL) Ritalinic acid (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Sertraline (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Secobarbital (Low: 128 - 192 ng/mL; Mid: 640 - 960 ng/mL; High 3200 - 4800 ng/mL) Sufentanyl (Low: 9.4 - 9.6 ng/mL; Mid: 32 - 48 ng/mL; High: 160 - 240 ng/mL) Tapentadol (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Tramadol (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Temazepam (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Trimipramine (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Venlafaxine (Low: 32 - 48 ng /mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) Zolpidam-4-Carboxylic Acid (Low: 32 - 48 ng/mL; Mid: 160 - 240 ng/mL; High: 800 - 1200 ng/mL) 2. Review of the 2018 toxicology quality control records revealed no documentation of the laboratory establishing the above acceptable quality control ranges. 3. An interview with testing person #1 on 10/10/18 at 1115 hours in the laboratory confirmed the above findings. She stated that the laboratory used the target value +/- 25%, but the laboratory did not establish them.
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 review of the laboratory policy, establishment studies, patient final reports, and confirmed in interview, the laboratory director failed to ensure the laboratory documented a complete stability study for urine confirmatory toxicology testing on the API-3000 LC/MS/MS toxicology analyzer. Refer to D5311
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 observations, review of the laboratory establishment studies, laboratory quality control records and patient logs, and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete establishment studies for urine toxicology confirmatory testing on the API-3000 LC/MS/MS toxicology analyzer. 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 the laboratory policy, laboratory quality control records, laboratory patient records, and confirmed in interview, the laboratory director failed to ensure the laboratory established the quality control (QC) acceptable range for the API-3000 LC/MS/MS toxicology analyzer. Refer to D5469
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the laboratory competency records and confirmed in interview, the technical supervisor failed to document competency assessment for quality control and preventive maintenance records. Findings were: 1. Review of the 2017 and 2018 competency records revealed 1 of 1 testing person (TP #1) with no documentation of competency for 2 of 2 annual competency assessment for quality control and preventative maintenance for the API-3000 LC/MS/MS toxicology analyzer. 2. An interview with the general supervisor on 10/10/18 at 0955 hours in the laboratory confirmed the above findings.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory competency records and confirmed in interview, the technical supervisor failed to document competency assessment of test performance through testing previously analyzed specimens, internal blind testing or external proficiency testing samples. Findings were: 1. Review of the 2017 and 2018 competency records revealed 1 of 1 testing person (TP #1) with no documentation of competency for 2 of 2 annual competency assessment of test performance through testing previously analyzed specimens, internal blind testing or external proficiency testing samples for the API-3000 LC/MS/MS toxicology analyzer. 2. An interview with the general supervisor on 10/10/18 at 0955 hours in the laboratory confirmed the above findings.