Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2275807	06/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Etx Diagnostics, Llc	12849 Capricorn St, Stafford, 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	Based on the onsite survey conducted 06/06/2023 to 06/07/2023, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1250 Condition: Analytic systems The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory.
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: I. Based on surveyor observation, review of laboratory policy, patient test records, and confirmed in interview, the laboratory failed to define conditions for specimen storage after collection and specimen conditions for transport to the laboratory for two of two urine toxicology testing methods on the Mindray BS-480 chemistry analyzer and the Agilent Tech 6420 LCMS analyzer, for 75 of 75 patients reviewed since testing began on May 1, 2023 to June 2, 2023. The findings included: 1. In a tour of the laboratory on 6/6/2023 at 09:10 hours, the surveyor observed the two following analyzers used in toxicology testing: Mindray BS-480 Chemistry Analyzer Agilent Tech 6420 LCMS Analyzer Surveyor queried if all patient samples were received from different facilities and the technical supervisor (TS 1) confirmed that they were collected off-site before being submitted to the laboratory for testing. 2. Based on a review of the laboratory policy titled "Specimen Collection and Handling", section 5 "Procedures", subsections 5.1 and 5.2 "Toxicology Specimen Collection" and "Specimen

Transport", respectively, did not include specimen storage instructions after collection or specimen transport requirements for delivery to the laboratory. 3. Review of laboratory orders from May 1, 2023, to June 2, 2023, had the following 75 patients submitted to the laboratory for testing: Specimen ID - Day Submitted for Testing ET23-0000039 05-01-2023 ET23-0000040 05-01-2023 ET23-0000041 05-01-2023 ET23-0000042 05-01-2023 ET23-0000044 05-01-2023 ET23-0000045 05-01-2023 ET23-0000046 05-01-2023 ET23-0000047 05-01-2023 ET23-0000048 05-01-2023 ET23-0000049 05-01-2023 ET23-0000050 05-01-2023 ET23-0000058 05-05-2023 ET23-0000059 05-05-2023 ET23-0000060 05-05-2023 ET23-0000061 05-05-2023 ET23-0000062 05-05-2023 ET23-0000063 05-05-2023 ET23-0000064 05-05-2023 ET23-0000065 05-05-2023 ET23-0000066 05-05-2023 ET23-0000068 05-09-2023 ET23-0000069 05-09-2023 ET23-0000070 05-09-2023 ET23-0000071 05-09-2023 ET23-0000072 05-09-2023 ET23-0000073 05-09-2023 ET23-0000074 05-09-2023 ET23-0000075 05-09-2023 ET23-0000076 05-09-2023 ET23-0000077 05-09-2023 ET23-0000078 05-09-2023 ET23-0000079 05-16-2023 ET23-0000080 05-16-2023 ET23-0000081 05-16-2023 ET23-0000082 05-19-2023 ET23-0000083 05-19-2023 ET23-0000084 05-19-2023 ET23-0000085 05-19-2023 ET23-0000086 05-19-2023 ET23-0000087 05-19-2023 ET23-0000088 05-19-2023 ET23-0000089 05-19-2023 ET23-0000090 05-19-2023 ET23-0000091 05-19-2023 ET23-0000092 05-19-2023 ET23-0000093 05-19-2023 ET23-0000094 05-19-2023 ET23-0000095 05-19-2023 ET23-0000096 05-19-2023 ET23-0000097 05-26-2023 ET23-0000098 05-26-2023 ET23-0000099 05-26-2023 ET23-0000100 05-26-2023 ET23-0000101 05-26-2023 ET23-0000102 05-26-2023 ET23-0000103 05-26-2023 ET23-0000104 05-26-2023 ET23-0000105 05-26-2023 ET23-0000106 05-26-2023 ET23-0000107 05-26-2023 ET23-0000108 05-26-2023 ET23-0000109 05-26-2023 ET23-0000110 05-26-2023 ET23-0000111 05-26-2023 ET23-0000112 05-26-2023 ET23-0000113 06-02-2023 ET23-0000114 06-02-2023 ET23-0000115 06-02-2023 ET23-0000116 06-02-2023 ET23-0000117 06-02-2023 ET23-0000118 06-02-2023 ET23-0000119 06-02-2023 ET23-0000120 06-02-2023 ET23-0000121 06-02-2023 ET23-0000122 06-02-2023 4. In an interview on 6/7/2023 at 14:40 hours, in the laboratory, the Chief Consulting Officer (CCO) and TS 1 confirmed that specimen storage and transport had not been established for urine toxicology testing on the BS480 Mindray chemistry analyzer and the Agilent Tech 6420 LCMS analyzer. II. Based on a review of laboratory policy, patient test records, and confirmed in an interview, the laboratory failed to follow its policy for the acceptable testing time, from specimen collection, for testing on the Agilent Tech 6420 LCMS (liquid chromatography-mass spectroscopy) analyzer for 6 of 64 patients reviewed in May 2023. The findings included: 1. Review of the laboratory policy titled "Specimen Collection and Handling", section 5.4 "Specimen Storage", stated the following: "Samples are to be stored refrigerated prior to testing. Samples may be stored for up to 7 days refrigerated at 2-8 (degrees) Celsius (C) after date of collection prior to initial testing. Samples may be stored at -20(degrees) C for up to 30 days after collection, frozen samples stored at -20(degrees) for 30 days may be used for testing." 2. Review of patient test records had the following 6 patients tested on the BS480 Mindray Chemistry analyzer after 7 days following the date of collection: Patient ID ET23-0000061, date collected 5/1/2023, date tested 5/10/2023 - 1 days elapsed Patient ID ET23-0000062, date collected 5/1/2023, date tested 5/10 /2023 - 1 days elapsed Patient ID ET23-0000079, date collected 5/4/2023, date tested 5 /16/2023 - 4 days elapsed Patient ID ET23-0000058, date collected 5/4/2023, date tested 5/16/2023 - 4 days elapsed Patient ID ET23-0000077, date collected 5/4/2023, date tested 5/16/2023 - 4 days elapsed Patient ID ET23-0000089, date collected 5/16 /2023, date tested 5/26/2023 - 2 days elapsed 3. In an interview on 6/7/2023 at 09:15 hours, in the laboratory, the technical supervisor (TS 1) confirmed that patients had been kept in the refrigerator prior to testing, and that they had been tested beyond the

	seven days after collection.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observation, specimen requirements, review of the Centers for Medicaid and Medicare Services (CMS) form 116, the U.S. Food and Drug Administration (FDA) website, laboratory documents, op and confirmed in interviews, the laboratory failed to meet requirements for analytic systems, as evidence by: 1. The laboratory failed to monitor storage temperature for seven of seven pallets of laboratory supplies observed on 6/6/2023. Refer to D5413. 2. The laboratory failed to establish test system performance specifications to include specimen transport and storage to ensure accurate and reliable testing for one of one laboratory developed test (LDT) for Liquid Chromatography Mass Spectrometry (LC-MS/MS) Toxicology testing on urine. Refer to D5423 I. 3. The laboratory failed to establish test system performance specifications to include interfering substances, specimen integrity over time to include various storage conditions in transit and upon receipt into the laboratory to ensure accurate and reliable testing for ten of ten FDA modified high complexity tests performed on the BS480 Mindray chemistry analyzer performing urine toxicology screens since testing began on May 1, 2023. Refer to D5423 II. 5. The laboratory failed to document daily maintenance for two of four days when patients were being tested on the BS480 Mindray Chemistry Analyzer in May 2023. Refer to D5431. 6. The laboratory failed to have a function check in place that ensured one of one centrifuge in use for patient testing was accurate and reliable prior to reporting 64 of 64 patients tested on the Agilent Tech 6420 Liquid Chromatography Mass Spectrometry (LC-MS/MS) for urine toxicology screen testing. Refer to D5435.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview the laboratory failed to monitor storage temperature for seven of seven pallets of laboratory supplies observed on 6/6/2023. The findings included: 1. In the upstairs storage room on 6/6/2023 at 11: 25 hours, the surveyor observed the following laboratory supplies and their

	corresponding storage requirements as listed on the label: 1 opened pallet of 92 and 1 unopened pallet of 100 4.0 mL, BD Vacutainer C&S Preservation Urine tubes, storage temperature 4 - 25(degrees) Celsius (C) 5 unopened pallets of 50 10mL, greiner bio-one Z Urine No Additive tubes, storage temperature 4 - 25(degrees) C 2. In an interview on 6/6/2023 at 11:32 hours, in the laboratory, the technical supervisor stated that the laboratory was not monitoring the storage area upstairs where the above items were being stored.
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: I. Based on a review of the Centers for Medicaid and Medicare Services (CMS) form 116, the U.S. Food and Drug Administration (FDA) website, laboratory documents, and confirmed in an interview, the laboratory failed to establish test system performance specifications to include specimen transport and storage to ensure accurate and reliable testing for one of one laboratory developed test (LDT) for Liquid Chromatography Mass Spectrometry (LC-MS/MS) Toxicology testing on urine. The findings included: 1. Review of the CMS form 116, section VII "Non-Waived Testing" listed a urine drug test panel by the manufacturer "Lighthouse Lab Services" as a high complexity LDT to include the following 63 drug targets: 7-Amino clonazepam Acetaminophen Alpha Hydroxy-Alprazolam Alpha -PVP Alprazolam Amitriptyline Amphetamine Buprenorphine Buproprion Carisoprodol-SOMA Citalopram Cocaine Metabolite (benzoylecgonine) Codeine Cyclobenzaprine Desmethyldoxepin Duloxetine Fentanyl Fluoxetlne Gabapentin Heroin Metabolite (6MAM) Hydrocodone Hydromorphone Ketamine lorazepam MDA MDMA Meperidine Meprobamate Methadone Methadone Metabolite (EDDP-3,3) Methamphetamlne Methylphenidate Mirtazapine Morphine Naloxone Naltrexone Norbuprenorphine Nordiazepam-Dlazepam Norfentanyl Norhydrocodone Normeperidine Noroxycodone Noroxymorphone Nortriptyline O-Desmethyl- Cis-Tramadol Oxazepam Oxycodone Oxymorphone Paroxetlne Phencyclidine-PCP Phentermine Pregabalin Propoxyphene Sertraline Tapentadol Temazepam THC- 11-nor delta 9 carboxy Tramadol Venlafaxine Zolpidem 2. Review of the laboratory document titled "Liquid Chromatography Mass Spectrometry Validation: LCMS 1", performed 4/7/2023, did not include specimen stability studies to support instructions listed in the policy (refer to D5311 II). 3. Review of laboratory test records had 64 patients tested in May 2023: 5/1/2023: 11 ET23-0000039 ET23-0000040 ET23-0000041 ET23-0000042 ET23-0000044 ET23-0000045 ET23-0000046 ET23-0000048 ET23-0000047 ET23-0000049 ET23-0000050 5/10/2023: 19 ET23-0000058 ET23-0000059 ET23-0000060 ET23-0000061 ET23-0000063 ET23-0000064 ET23-0000065 ET23-0000066 ET23-0000068 ET23-0000069 ET23-0000070 ET23-

	0000071 ET23-0000072 ET23-0000073 ET23-0000074 ET23-0000075 ET23-0000076 ET23-0000077 ET23-0000078 5/16/2023: 3 ET23-0000079 ET23-0000080 ET23-0000081 5/22/2023: 15 ET23-0000082 ET23-0000083 ET23-0000084 ET23-0000085 ET23-0000086 ET23-0000087 ET23-0000088 ET23-0000089 ET23-0000090 ET23-0000091 ET23-0000092 ET23-0000093 ET23-0000094 ET23-0000095 ET23-0000096 5/26/2023: 16 ET23-0000097 ET23-0000098 ET23-0000099 ET23-0000100 ET23-0000101 ET23-0000102 ET23-0000103 ET23-0000104 ET23-0000105 ET23-0000106 ET23-0000107 ET23-0000108 ET23-0000109 ET23-0000110 ET23-0000111 ET23-0000112 4. In an interview on 6/7/2023 at 09:11 hours, in the laboratory, the Chief Consulting Officer confirmed that the laboratory did not include any specimen stability studies to ensure accurate and reliable testing for the urine toxicology testing on the Agilent 6420 LCMS analyzer. II. Based on a review of the Centers for Medicaid and Medicare Services (CMS) form 116, the U.S. Food and Drug Administration (FDA) website, laboratory documents, and confirmed in interview, the laboratory failed to establish test system performance specifications to include interfering substances, specimen integrity over time to include various storage conditions in transit and upon receipt into the laboratory to ensure accurate and reliable testing for ten of ten FDA modified high complexity tests performed on the BS480 Mindray chemistry analyzer performing urine toxicology screens since testing began on May 1, 2023. The findings included: 1. Review of the CMS form 116, section VII. "Non Waived Testing" listed a BS480 Mindray Chemistry Analyzer performing the following testing: Amphetamine Barbiturates Benzodiazepines Buprenorphine Opiates THC Cocaine Methadone Alcohol/Ethanol Creatinine/Ph 2. Review of the FDA test complexity database for the following reagent's intended use did not include use on the BS480 Mindray instrument, classifying each as and FDA modified test: DRI Amphetamines Assay - Thermo Scientific DRI Barbiturate Assay - Thermo Scientific DRI Benzodiazepine Assay - Thermo Scientific CEDIA Buprenorphine II Assay - Thermo Scientific DRI Opiate Assay - Thermo Scientific DRI Cannabinoid Assay - Thermo Scientific DRI Cocaine Metabolite Assay - Thermo Scientific DRI Methadone Assay - Thermo Scientific DRI Ethyl Alcohol Assay - Thermo Scientific DRI pH-Detect Test - Thermo Scientific 3. Review of the laboratory document titled "ETX: Validation Mindray BS 480" signed by the laboratory director on 4/21/2023, did not include analytical specificity to include interfering substance or specimen stability studies to ensure accurate and reliable test results. 4. Review of patient testing records have the following 45 patients tested on the BS480 Mindray Chemistry analyzer in May 2023: 05/10/2023 - 11 ET23-0000058 ET23-0000059 ET23-0000060 ET23-0000061 ET23-0000062 ET23-0000063 ET23-0000064 ET23-0000068 ET23-0000069 ET23-0000070 ET23-0000071 05/16/2023 - 3 ET23-0000079 ET23-0000080 ET23-0000081 05/22/2023 - 15 ET23-0000082 ET23-0000083 ET23-0000084 ET23-0000085 ET23-0000086 ET23-0000087 ET23-0000088 ET23-0000089 ET23-0000090 ET23-0000091 ET23-0000092 ET23-0000093 ET23-0000094 ET23-0000095 ET23-0000096 05/26/2023 - 16 ET23-0000097 ET23-0000098 ET23-0000099 ET23-0000100 ET23-0000101 ET23-0000102 ET23-0000103 ET23-0000104 ET23-0000105 ET23-0000106 ET23-0000107 ET23-0000108 ET23-0000109 ET23-0000110 ET23-0000111 ET23-0000112 5. In an interview on 6/6/2023 at 14:45, in the laboratory, the Chief Consulting Officer (CCO) stated the establishment studies had not been completed and that the laboratory did not realize that reagents were not FDA-approved for the BS480 Mindray analyzer.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the instrument operator's manual guide, laboratory maintenance records, patient test records, and confirmed in an interview, the laboratory failed to document daily maintenance for two of four days when patients were being tested on the BS480 Mindray Chemistry Analyzer in May 2023. The findings included: 1. Review of the "BS-480 Clinical Analyzer Operator's Manual", section 16 "Maintenance", subsection 16.4.3 "Scheduled Maintenance Procedures" listed the following daily maintenance: "Daily maintenance: - Check probes/mixers/wash wells - Check Sample/ reagent syringes - Check deionized water connections - Check waste tube connection - Check concentrated wash solution - Check sample probe wash solution - Clean electrode tubes" 2. Review of patient testing records had the following 14 patients tested on the BS-480 Mindray chemistry analyzer with no documented daily maintenance: 05/10/2023 - 11 patients ET23-0000058 ET23-0000059 ET23-0000060 ET23-0000061 ET23-0000062 ET23-0000063 ET23-0000064 ET23-0000068 ET23-0000069 ET23-0000070 ET23-0000071 05/16/2023 - 3 patients ET23-0000079 ET23-0000080 ET23-0000081 3. In an interview on 6/6 /2023 at 14:25 hours, in the laboratory, the technical supervisor (TS 1) confirmed that daily maintenance was not documented for the above days when patients were being tested on the BS-480 Mindray Chemistry Analyzer.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory failed to have a function check in place that ensured one of one centrifuge in use for patient testing was accurate and reliable prior to reporting 64 of 64 patients tested on the Agilent Tech 6420 Liquid Chromatography Mass Spectrometry (LC-MS/MS) for urine toxicology screen testing. The findings included: 1. In a tour of the laboratory on 6/7/2023 at 13:35 hours, the surveyor observed the following centrifuge near a specimen processing station: Hermle Benchmark Z307, SN: 872250006 2. Review of the laboratory procedure titled "Sample Preparation", section 4 "Procedures" had the following equipment needed: "Centrifuge capable of ~3400 - 3600 RPM and RCF ~1050 with 96 well plates" Surveyor queried on 6/7 /2023 at 13:37 hours, in the laboratory, for the tachometer records, and none were provided. 3. Review of laboratory test records had 64 patients tested since May 1, 2023 on the Agilent Tech 64200 LCMS for urine toxicology screen testing: 5/1/2023:

	11 ET23-0000039 ET23-0000040 ET23-0000041 ET23-0000042 ET23-0000044 ET23-0000045 ET23-0000046 ET23-0000048 ET23-0000047 ET23-0000049 ET23-0000050 5/10/2023: 19 ET23-0000058 ET23-0000059 ET23-0000060 ET23-0000061 ET23-0000063 ET23-0000064 ET23-0000065 ET23-0000066 ET23-0000068 ET23-0000069 ET23-0000070 ET23-0000071 ET23-0000072 ET23-0000073 ET23-0000074 ET23-0000075 ET23-0000076 ET23-0000077 ET23-0000078 5/16/2023: 3 ET23-0000079 ET23-0000080 ET23-0000081 5/22/2023: 15 ET23-0000082 ET23-0000083 ET23-0000084 ET23-0000085 ET23-0000086 ET23-0000087 ET23-0000088 ET23-0000089 ET23-0000090 ET23-0000091 ET23-0000092 ET23-0000093 ET23-0000094 ET23-0000095 ET23-0000096 5/26/2023: 16 ET23-0000097 ET23-0000098 ET23-0000099 ET23-0000100 ET23-0000101 ET23-0000102 ET23-0000103 ET23-0000104 ET23-0000105 ET23-0000106 ET23-0000107 ET23-0000108 ET23-0000109 ET23-0000110 ET23-0000111 ET23-0000112 4. In an interview on 6/7/2023 at 14:03 hours, in the laboratory, the Chief Consulting Officer was unable to provide evidence that verified the actual centrifuge speed matched the speed required for the specimen processing was accurate and reliable prior to being put into patient testing.
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 the Centers for Medicaid and Medicare Services (CMS) form 116, the U.S. Food and Drug Administration (FDA) website, laboratory documents, and confirmed in an interview, the laboratory director failed to ensure that the establishment studies were completed for two of two test systems used in toxicology testing to include test system performance specifications for specimen integrity over time and storage conditions since testing began in May 2023 (Refer to D5423 I & II) and analytic specificity to interfering substances for one of two testing platforms in use for urine toxicology testing since testing began in May 2023 (Refer to D5423 II).