Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2309473	06/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Texas Health Care, Pllc	1001 12th Ave Suite 240, Fort Worth, 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 to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Indiko Plus quality control (QC) records, corrective action documentation, patient test records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 24 of 24 patients in 2024 (November) and 162 of 162 patients in 2025 (May-June). Findings included: 1. Review of the laboratory's policy "THC: Quality Control", approved by the laboratory director 08/21/2024, stated: "6. Procedures ... Step 6.1 Action EIA Analyzer Step 6.1.1 Responsible Laboratory Technologist Action Daily verify that quality control values are within allowable tolerance ranges (see instrument specific SLPs and manufacturer's instructions and/or inserts). In the event that an analyte's overall status is designated "FAIL" take the appropriate steps (see 'trouble shooting' below, instrument specific SLPs and/or manufacturer's instructions or inserts) and document any additional corrective and/or preventative actions. Daily QC failures (errors) and corrective (remedial) actions should be recorded in the electronic Daily QC log. No patient results are to be reported until the problem has been resolved. Outliers of QC must be documented,

and repeat controls recorded as well. A statement such as "OK" or "Pass" should be documented. Note any trends or shifts, and if warranted, steps taken to rectify the problem. Trouble shooting steps: a. If any test(s) falls outside of the acceptable 3 SD range, repeat the failed level or control for the test(R) that exceeded 3 SD. b. If the test (s) fails on the second run, pipette fresh control and rerun the failed control. c. If the test still falls outside of the acceptable range, recalibrate the test(s) and repeat all levels of control for the test that exceeds 3 SD using fresh materials. ***Under no circumstances will patient test results will be reported unless QC is within acceptable limits*** Additional Troubleshooting Steps: b. [sic] Check for clerical errors. c. [sic] Check to make sure proper techniques were used. d. [sic] Check preventative maintenance logs to ensure proper maintenance of the instrument if applicable. e. [sic] Check dates of expiration of materials and general supplies. f. [sic] Check for proper temperature if instrument is temperature sensitive. g. [sic] Check QC records for trends, shifts, etc." The policy did not state to evaluate patients when test systems adjustments were made for QC failures since the last acceptable QC run. 2. Review of Indiko quality control (QC) records, corrective action documentation and patient test results revealed test system adjustments performed for the following sampling of QC test events in November 2024, May through June 2025: Utak QC Level 1 lot #D4785 11/15/2024 QC Level 1 8:11 am QC failed for cocaine 8:28 am QC was repeated and failed 9:02 am QC was repeated and passed Corrective action documentation stated: "Cocaine Level 1 failed QC. It failed on rerun as well. Next, fresh reagent with new lot # was poured off. Calibration & QC ran. QC passed." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (11/14/2024): Patient IDs: UR24-1313, UR24-1314, UR24-1315, UR24-1316, UR24-1317, UR24-1318, UR24-1319, UR24-1320, UR24-1321, UR24-1322, UR24-1323, UR24-1324, UR24-1325, UR24-1326, UR24-1327, UR24-1328, UR24-1329, UR24-1330, UR24-1331, UR24-1332, UR24-1333, UR24-1334, UR24-1335, UR24-1336, UR24-1337, UR24-1338, UR24-1339, UR24-1340, UR24-1341, UR24-1342, UR24-1343, UR24-1344, UR24-1345 EIA Custom 1 QC Lot # T25055A EIA Custom 2 QC Lot # T25055B 05/12/2025 QC Custom 1 10:31 am QC failed for Buprenorphine 10:47 am QC was repeated and passed Corrective action documentation stated: "Buprenorphine Level 1 was outside 2SD. Passed on calibration and run." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (05/09/2025): Patient IDs: UR25-3445, UR25-3446, UR25-3447, UR25-3448, UR25-3449, UR25-3450, UR25-3451, UR25-3452, UR25-3453, UR25-3454, UR25-3455, UR25-3456, UR25-3457, UR25-3458, UR25-3459, UR25-3460, UR25-3461, UR25-3462, UR25-3463, UR25-3464, UR25-3465, UR25-3466, UR25-3467, UR25-3468, UR25-3469, UR25-3470, UR25-3471, UR25-3472, UR25-3473, UR25-3474, UR25-3475, UR25-3476, UR25-3477, UR25-3478, UR25-3479, UR25-3480, UR25-3481 05/30/2025 QC Custom 1 9:53 am QC failed for Buprenorphine 10:10 am QC was repeated and failed for Buprenorphine 10:56 am QC was repeated and failed for Buprenorphine 11:26 am QC was repeated and failed for Buprenorphine 11:41 am QC was repeated and passed Corrective action documentation stated: "Benzodiazepine, Buprenorphine, Cocaine and THC Level 1 failed QC. Benzo, Cocaine & THC passed on 1st rerun. Bup was recalibrated and QC was run. Passed on rerun." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (05/29/2025): Patient IDs: UR25-3850, UR25-3860, UR25-3877, UR25-3882, UR25-3890, UR25-3900, UR25-3933, UR25-3935, UR25-3936, UR25-3937, UR25-3938, UR25-3939, UR25-3940, UR25-3941, UR25-3942 06 /06/2025 QC Custom 1 10:21 am QC failed for Barbiturate 10:39 am QC was repeated and failed for Barbiturate 11:25 am QC was repeated and passed 10:23 am

QC failed for Buprenorphine 10:41 am QC was repeated and failed for Buprenorphine 11:27 am QC was repeated and passed QC Custom 2 10:22 am QC failed for Methadone 10:40 am QC was repeated and failed for Methadone 11:26 am QC was repeated and passed 10:23 am QC failed for Buprenorphine 10:41 am QC was repeated and failed for Buprenorphine 11:27 am QC was repeated and passed 10:24 am QC failed for Amphetamine 10:40 am QC was repeated and failed for Amphetamine 11:26 am QC was repeated and passed Corrective action documentation stated: "Amphetamine, Barbiturate, Benzodiazepine, Methodone & Buprenorphine failed QC. Benz passed on first rerun. Amph, Bup, Barb & Methd were recalibrated. QC passed upon rerun after calibration." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (06/05/2025): Patient IDs: UR25-4102, UR25-4103, UR25-4104, UR25-4105, UR25-4106, UR25-4107, UR25-4108, UR25-4109, UR25-4110, UR25-4111, UR25-4112, UR25-4113, UR25-4114, UR25-4115, UR25-4116, UR25-4117, UR25-4118, UR25-4119, UR25-4120, UR25-4121, UR25-4122, UR25-4123, UR25-41224, UR25-4125, UR25-4126, UR25-4127, UR25-4128, UR25-4129, UR25-4130, UR25-4131, UR25-4132, UR25-4133, UR25-4134, UR25-4135, UR25-4136, UR25-4045, UR25-4059, UR25-4084 06/10/2025 QC Custom 1 9:22 am QC failed for Benzodiazepine 9:40 am QC was repeated and failed for Benzodiazepine 10:17 am QC was repeated and passed 9:23 am QC failed for Amphetamine 9:40 am QC was repeated and failed for Amphetamine 10:17 am QC was repeated and passed 9:25 am QC failed for Opiates 9:40 am QC was repeated and failed for Opiates 10:17 am QC was repeated and passed 9:24 am QC failed for Buprenorphine 9:41 am QC was repeated and failed for Buprenorphine 10:19 am QC was repeated and passed QC Custom 2 9:24 am QC failed for Amphetamine 9:40 am QC was repeated and failed for Amphetamine 10:17 am QC was repeated and passed Corrective action documentation stated: "Bup, Opiates, Amphetamine, Benzodiazepine and Cocaine and Barbiturate failed QC. Cocaine and Barbs passed on first rerun. Bup, Opiates, Amph and Benz were calibrated and QC was rerun. Everything passed." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (06/09/2025): Patient IDs: UR25-4177, UR25-4178, UR25-4179, UR25-4180, UR25-4181, UR25-4182, UR25-4183, UR25-4184, UR25-4185, UR25-4186, UR25-4187, UR25-4188, UR25-4189, UR25-4190, UR25-4191, UR25-4192, UR25-4193, UR25-4194, UR25-4195, UR25-4196, UR25-4197, UR25-4198, UR25-4199, UR25-4200, UR25-4201, UR25-4202, UR25-4203, UR25-4204, UR25-4205, UR25-4206, UR25-4207, UR25-4208, UR25-4209, UR25-4210, UR25-4211, UR25-4212, UR25-4213, UR25-4214, UR25-4215, UR25-4216, UR25-4217, UR25-4218, UR25-4219, UR25-4220, UR25-4221, UR25-4222, UR25-4223, UR25-4224, UR25-4225, UR25-4226, UR25-4227 06/11/2025 QC Custom 1 9:10 am QC failed for Cocaine 9:29 am QC was repeated and failed for Cocaine 10:26 am QC was repeated and passed Corrective action documentation stated: "Cocaine & Benzo Level 1 were outside 2SD. Benz passed on 1st rerun. Cocaine was calibrated & QC was rerun. QC passed after calibration & rerunning." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (06/10/2025): Patient IDs: UR25-4228, UR25-4229, UR25-4230, UR25-4231, UR25-4232, UR25-4233, UR25-4234, UR25-4235, UR25-4236, UR25-4237, UR25-4238, UR25-4239, UR25-4240, UR25-4241, UR25-4242, UR25-4243, UR25-4244, UR25-4245, UR25-4246, UR25-4247, UR25-4248 3. During an interview on 06/11/2025 at 2:23 pm, the Technical Supervisor confirmed that patients were not evaluated since the last acceptable QC run when test system adjustments were performed on the Indiko toxicology analyzer. Word Key: Bup - Buprenorphine Amph - Amphetamine THC - Tetrahydrocannabinol SD- standard

	deviation Benzo/Benz- Benzodiazepine Barb/Barbs - Barbiturate Methd - Methadone
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory procedure, quality control records, and confirmed in interview, the laboratory failed to follow written policies to assess and monitor analytic systems for five of five months in 2025 (January-May). Findings Included: 1. During a tour of the laboratory on 06/11/2025 at 09:20 AM, the surveyor observed one LCMS chemistry analyzer performing patient testing (Serial Number: SG12457105). 2. Review of laboratory policy, "Quality Control" (Approved by the Laboratory Director on 08/21/2024) revealed the following: " ...6.2 LCMS ... 6.2.2 Laboratory Director or Designee Monthly perform review of the data collected for the Levy-Jennings plots to identify biases and trends for QC's used in confirmatory testing by LC/MS." 3. Review of LCMS laboratory quality control data in 2025, revealed the laboratory director failed to document monthly review for five of five months in 2025 (January-May). The laboratory was asked to provide documentation of laboratory director monthly review, or designation of monthly quality control review duty, for the above months in 2025, and none was provided. 4. During an interview on 06/11/2025 at 01:15 PM, with the facility consultant in the laboratory, the consultant confirmed the laboratory failed to follow written policies to assess and monitor analytic systems for five of five months in 2025 (January-May). Word Key LCMS- Liquid Chromatography Mass Spectrometry QC- Quality Control
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy CMS (Center for Medicare & Medicaid Services) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance for one of sixteen Testing Persons (TP-2) responsible for high complexity testing at least semiannually during the first year that testing persons analyzed patient specimens. Findings included: 1. Review of the laboratory's policy "Gen 9 Gen: Competency" stated: "5. Procedures: Step 5.1 Responsible Laboratory Director/Designee Action Training of laboratory personnel performing non-waived testing by qualified personnel occurs prior to performance of patient testing on any new methodology, instrumentation, or procedure. Training and Competency documentation is maintained for a period of at least 2 years and available at all times. SYSTEM LEVEL PROCEDURE: Competency 5.2 Competency is evaluated during on-the-job training, proficiency testing, and randomly during the technical audits of test methods. Competency is assessed and documented prior to initiating testing, at six months during the first year

	of employment, at one year of employment and annually thereafter ... 2. Review of the submitted CMS 209 form revealed Testing Person-2 (TP-2) listed to perform high complexity testing. 3. Review of personnel records from 2024 and 2025 revealed the following: TP-2 Training documentation for toxicology data analysis and review: training dates 07/2024 and 10/2024 Competency Assessment - Toxicology Data Analysis and Data Review: 11/04/2024 Observer: Completed by someone who was NOT delegated on the CMS-209 as a Technical Supervisor Competency Assessment - Toxicology Data Analysis and Data Review: 04/30/2025 Observer: Completed by Testing Person-14 who was NOT delegated on the CMS-209 as a Technical Supervisor The TS failed to evaluate and document performance at least semiannually during the first year of patient testing. 4. During an interview on 06/11/2025 at 11:48 a.m., the Quality Consultant, after a review of records confirmed the above findings.