Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2117237	05/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lakeway Complete Care Llc	1518 Ranch Road 620 South,Suite 200, Lakeway, 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 surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.801 Condition: Enrollment and testing of samples 493.1403 Condition: Laboratories Performing Moderate Complexity Testing; laboratory director 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; technical consultant 493.1421 Condition: Laboratories Performing Moderate Complexity Testing; testing personnel 493.1250 Condition: Analytic Systems
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Observations, review of the laboratory proficiency testing records, review of the CMS report 155 Individual Laboraotry Profile and interview of facility personnel found that the laboratory failed to enroll in a proficiency testing program for all analytes tested in the specialty of Chemistry. Findings included: 1. Observations made during the tour of the facility found that the laboratory used the MetLac 12 Panel (Abaxis Piccolo) and the One Step Drug Screen Test Card (moderately complex procedures) for testing patient specimens. 2. Review of the American Proficiency Institute (API) proficiency testing records from 2016 third event through the 2018 first event (three events per

	year) found that the laboratory did not enroll and participate in an appropriate proficiency testing program for non waived Chemistry and Toxicology analytes as follows: a. Chemistry - The laboratory failed to enroll in a nonwaived proficiency testing program for testing performed using the moderately complex Abaxis Piccolo MetLac12 Panel Reagent Disc. The MetLac Panel 12 Reagent Disc includes Albumin, Calcium, Chloride, Creatinine, Glucose, Lactate, Magnesium, Phosphorous, Sodium. Carbon Dioxide and Blood urea nitrogen. b. Toxicology - The laboratory failed to enroll in a nonwaived proficiency testing program for testing performed using the moderately complex One Step Drug Screen Test Card for urine drug screens. 3. Review of the CMS Report 155 Laboratory Individual Profile found no results reported for regulated analytes included in the moderately complex Abaxis MetLac 12 Panel. 4. Interview of Technical Consultant 2 on the CMS Report 209 conducted on May 16, 2018 at 11:21 confirmed that the laboratory did not participate in a nonwaived Chemistry proficiency testing program for MetLac 12 Panel Reagent Disc. She stated that" the laboratory started using the MetLac 12 Panel Reagent Disc in July, 2016 but did not enroll in a nonwaived Chemistry proficiency testing program until 2018, and they did not report Phosphorous and Magnesium." At 11:54 AM, Technical Consultant 2 went on to say that it was the laboratory's practice to" report analytes from the CMP disc and add the non common analytes from the liver panel" to complete the Chemistry proficiency testing results submitted to the Proficiency testing agency. The Technical Consultant also confirmed that the laboratory did not enroll in a proficiency testing program for urine drug screens because they were not supposed to be using the OneStep Drug Screen Test card for testing patients.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Observations, review of the laboratory proficiency testing records, review of the CMS report 155 Individual Laboratory Profile and interview of facility personnel found that the laboratory quality assessment program failed to identify that the laboratory was enrolled in an appropriate proficiency testing program for nonwaived analytes tested in the specialty of Chemistry.
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: Review of laboratory records and interview of facility personnel found that the

	laboratory failed to ensure that quality control procedures were tested each day when the non waived Multi Drug Screen Test Panel urine drug screen test kits were used for patient testing. (see D5449)
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Observations, review of manufacturer's package insert, policies and procedures, patient test records and interview of facility personnel found that the laboratory failed to have a written procedure available to all testing personnel for defining the frequency and type of controls to be used with the Multi Drug Screen Test card for testing patient specimens for drugs of abuse. The findings included: 1. Observations made during the tour of the facility found that the laboratory was currently using the Multi Drug Screen Test card (COC/AMP/mAMP/THC/MTD/MOP/PCP/BAR/BZO /TCA) lot DOA7060596 expiration 2019-06-30 (rec'd 04/10/2018). The label read" This assay provides only a preliminary result. A quantitative analytical method is needed to obtain a confirmed result." 2. Review of the Manufacturer's package insert found under the heading QUALITY CONTROL - " A procedural control is included in the test. A line appearing in the Control Region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance." 3. Review of policies and procedures found no additional policy or procedure for the use of this test kit, defining the number and frequency of quality control materials. The laboratory had not developed an Individualized Quality Control Plan (IQCP) to decrease the frequency of quality control testing to ensure accurate and reliable results. 4. Review of patient test records found that the laboratory tested 4 patient specimens between the date the test kit was opened (04/27/2018) and June 15, 2018: Specimen ID 042701 - tested April 27, 2018 Specimen ID 050102 - tested May 1, 2018 Specimen ID 050403 - tested May 4, 2018 Specimen ID 050902 - tested May 9, 2018 5. Interview of Technical Consultant 2 on the CMS Report 209 Laboratory Personnel report conducted on June 16, 2018 at 2:03 PM confirmed that the laboratory

	did not test a negative and positive quality control when using the Multi Drug Screen Test card and they had not developed an IQCP to decrease the frequency of quality control testing when using the kit. She went on to say that the laboratory was not supposed to be using this test kit.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Observations, review of manufacturer's package insert, policies and procedures, patient test records and interview of facility personnel found that the laboratory failed to test a negative and positive control each day of patient testing when using the Multi Drug Screen Test card for testing patient specimens for drugs of abuse. The findings included: 1. Observations made during the tour of the facility found that the laboratory was currently using the Multi Drug Screen Test card (COC/AMP/mAMP/THC/MTD /MOP/PCP/BAR/BZO/TCA) lot DOA7060596 expiration 2019-06-30 (rec'd 04/10 /2018). The label read" This assay provides only a preliminary result. A quantitative analytical method is needed to obtain a confirmed result." 2. Review of the Manufacturer's package insert found under the heading QUALITY CONTROL - " A procedural control is included in the test. A line appearing in the Control Region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance." 3. Review of policies and procedures found no additional policy or procedure for the use of this test kit, defining the number and frequency of quality control materials. The laboratory had not developed an Individualized Quality Control Plan (IQCP) to decrease the frequency of quality control testing to ensure accurate and reliable results. 4. Review of patient test records found that the laboratory tested 4 patient specimens between the date the test kit was opened (04/27/2018) and June 15, 2018: Specimen ID 042701 - tested April 27, 2018 Specimen ID 050102 - tested May 1, 2018 Specimen ID 050403 - tested May 4, 2018 Specimen ID 050902 - tested May 9, 2018 5. Interview of Technical Consultant 2 on the CMS Report 209 Laboratory Personnel report conducted on June 16, 2018 at 2:03 PM confirmed that the laboratory did not test a negative and positive quality control when using the Multi Drug Screen Test card and they had not developed an IQCP to decrease the frequency of quality control testing when using the kit. She went on to say that the laboratory was not supposed to be using this test kit.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document

	all analytic systems assessment activities. This STANDARD is not met as evidenced by: Observations, review of manufacturer's package insert, policies and procedures, patient test records and interview of facility personnel found that thequality assessment proagram failed to identify that quality control procedures were not perfomed each day of patient testing when using the Multi Drug Screen Test card for testing patient specimens for drugs of abuse. (see D 5449)
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observations, review of quality control records, review of calibration records, review patient test records, review of corrective action logs, review of package inserts and interview of facility personnel found that the laboratory director failed to provide technical and scientific oversight of the laboratory. (See D6015, D6020, D6021, and D6031)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Review of the CMS 155 Individual Laboratory Profile, Proficiency testing records, and interview of facility personnel found that the laboratory director failed to ensure that the laboratory was enrolled and participated in an approved proficiency testing program for nonwaived testing in Chemistry and Toxicology. (see D 2000)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Observations, review of manufacturer's package insert, policies and procedures, patient test records and interview of facility personnel found that the laboratory director failed to ensure that testing personnel tested a negative and positive control each day of patient testing when using the One Step Drug Screen Test card for testing patient specimens for drugs of abuse. (see D 5403 and D 5449)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Observations, review of the laboratory proficiency testing records, review of the CMS report 155 Individual Laboratory Profile, patient test records and interview of facility personnel found that the laboratory director failed to ensure the quality assessment program identified and corrected problems in proficiency testing enrollment (see D 5291) and in testing negative and positive controls when using non waived test kits to perform urine drug screen testing (see D5449).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Observations, review of manufacturer's package insert, policies and procedures, patient test records and interview of facility personnel found that the laboratory director failed to ensure that an approved written procedure defining quality control procedures for the Multi Drug Screen Test card was available to all testing personnel testing patient specimens for drugs of abuse. (see D 5403)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

	Based on observations, review of quality control records, review of calibration records, review of patient test records, review of corrective action logs, review of package inserts and interview of facility personnel found that the technical consultant failed to provide technical and scientific oversight of the laboratory. (See D6041, D6042, and D6054)
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Review of the CMS 155 Individual Laboratory Profile, Proficiency testing records, and interview of facility personnel found that the technical consultant failed to ensure that the laboratory was enrolled and participated in an approved proficiency testing program for nonwaived testing in Chemistry and Toxicology. (see D 2000)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Observations, review of manufacturer's package insert, policies and procedures, patient test records and interview of facility personnel found that the Technical Consultant failed to ensure that testing personnel tested a negative and positive control each day of patient testing when using the One Step Drug Screen Test card for testing patient specimens for drugs of abuse. (see D 5449)
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Review of personnel records found that the technical consultant failed to ensure that competency assessments were completed on all testing personnel at least annually after their first year of testing patient specimens. One of 12 testing personnel had no annual competency assessment available for review. Findings included: 1. Review of personnel files found that Testing Person four listed on the CMS Report 209 Laboratory Personnel Report (date of hire 05/19/2016) . Initial training records were dated with a completion date of 11/6/2016. Six month competency assessment was

	documented as completed on 11/8/2016. There were no other competency assessments available for review. 2. Interview of Technical Consultant two listed on the CMS Report 209 Laboratory Personnel Report conducted on 05/16/2018 at 10:28 AM confirmed that the "previous nurse manager fell behind and did not get competency assessments done." Technical Consultant stated that she started working with the laboratory in June 2017. She went on to explain that "the competency assessment starts off with the employee beginning the paperwork with a self assessment as a starting point for discussion. Then the technical consultant signs off on the competency assessment."