Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2281633	07/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Le Health Llc	20851 Fm 1485, Suite I, New Caney, 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	An announced survey of the laboratory was conducted on 07/22/2026. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5300 - 42 C. F.R. 493.1240 Condition: Preanalytic systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 laboratory's policies/procedures, random specimen transport documents, quality assurance (QA) records and staff interview, the laboratory failed to monitor, evaluate and correct issues in overall quality of preanalytic systems for one of one test performed by the laboratory, Toxicology Screen. Findings included: 1. The laboratory failed to follow its own policies/procedures for specimen transport temperature. Refer to D5311A. 2. The laboratory failed to follow its own policies /procedures for specimen transport temperature documentation. Refer to D5311B. 3. The laboratory failed to ensure its QA had mechanisms in place to identify and correct issues in specimen transport and its documentation. Refer to D5391.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:
A. Based on review of laboratory's patient test records, laboratory's test menu, policies /procedures, specimen transport stability studies, random specimen transport documents and staff interview, the laboratory failed to follow its own policies /procedures for specimen transport temperature for eleven of fourteen specimens reviewed from May and June 2026 received for Toxicology Screen testing. Findings included: 1. Review of patient test records revealed the laboratory also performed testing for outside patients from sister facilities located throughout the area. 2. Review of laboratory's submitted test menu revealed the laboratory performed Toxicology Screen using the P500 Diatron analyzer. 3. Review of laboratory's policy/procedure "SOP 13: Specimen Collection and Labeling" (effective date: 10/03/2025) revealed: "4.3 Transport ... Store at 2-8C (Degrees Celsius) during transport, using cool packs if needed." 4. Review of laboratory's verification of specimen stability studies revealed the laboratory did not have documentation of verifying specimen transport stability studies at the above specified temperatures, or any other conditions. 5. Review of laboratory's random specimen transport documents from May and June 2026 revealed the following patients' samples were not transported at the required 2-8C [35.6-46.4F (Degrees Fahrenheit)]: Patient number:5422 Received 06/01/26 Transport temperature: 84F Patient number:10028 Received 06/01/26 Transport temperature:84F Patient number:12415 Received 06/03/26 Transport temperature:82F Patient number:12944 Received 06/03/26 Transport temperature:82F Patient number:9526 Received 06/03 /26 Transport temperature:82F Patient number: None, Date of Birth (DOB):11.19.84 Received 06/03/26 Transport temperature:82F Patient number:4272 Received 06/03 /26 Transport temperature:82F Patient number:4347 Received 06/03/26 Transport temperature:82F Patient number:7866 Received 06/03/26 Transport temperature:82F Patient number: None; DOB:12.05.64 Received 06/03/26 Transport temperature:82F Patient number:13014 Received 06/03/26 Transport temperature:82F 6. In an interview on 07/22/2026 at 1020 hours in the office, the laboratory's Technical Consultant stated that the laboratory does not use coolers/cool packs to maintain the required transport temperature, confirming the findings. B. Based on review of laboratory's policies/procedures, random specimen transport documents and staff interview the laboratory failed to follow its own policies/procedures for specimen transport temperature documentation for three of fourteen specimens reviewed from May and June 2026 received for Toxicology Screen testing. Findings included: 1. Review of laboratory's policy/procedure "SOP 13: Specimen Collection and Labeling" (effective date: 10/03/2025) revealed: "4.5 Documentation Maintain a specimen collection log in the LIS (Laboratory information System) or a secure binder including: Patient ID, specimen type, collection details, and transport conditions. 2. Review of laboratory's random specimen transport documents from May and June 2026 revealed the following three of fourteen patients did not have documentation of transport conditions for their samples: Patient number: None, Date of Birth (DOB):11 /02/1959 Collected 05/28/2026 Transport temperature: not documented Patient number: None, DOB:01/24/1953 Collected 05/28/2026 Transport temperature: not documented Patient number: None, Date of Birth (DOB):05/09/1953 Collected 05/28 /2026 Transport temperature: not documented 3. In an interview on 07/22/2026 at

	1020 hours in the office, the laboratory's Technical Consultant confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, random specimen transport documents, quality assurance (QA) records and staff interview, the laboratory failed to ensure its QA had mechanisms in place to identify and correct issues in specimen transport and its documentation for one of one test performed by the laboratory, Toxicology Screen. Refer to D5311 A and B.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer instructions and staff interview, the laboratory failed to ensure controls and calibrators were labeled with open dates and/or amended expiration dates for seven of seven reagents in use observed. Findings included: 1. Surveyor's observations on 07/22/2026 at 11:30 in the laboratory revealed the following reagents in use that did not have open date and/or amended expiration dates documented: 6-Acetylmorphine Urine Calibrator Lot number: E59563 Manufacturer expiration date: 2027-03-31 Open date/amended expiration date: not documented Fentanyl Urine Calibrator 1 Lot number: E57322 Manufacturer expiration date: 2026-07-31 Open date/amended expiration date: not documented Multi-drug Calibrator 1 Lot number: E59647 Manufacturer expiration date: 2026-09-30 Open date/amended expiration date: not documented Multi-drug Calibrators Lot number: E59754 Manufacturer expiration date: 2026-09-30 Open date /amended expiration date: not documented 6-Acetylmorphine Low Control Lot number: E59894 Manufacturer expiration date: 2027-03-31 Open date/amended expiration date: not documented 6-Acetylmorphine High Control Lot number: E59895 Manufacturer expiration date: 2027-03-31 Open date/amended expiration date: not documented Fentanyl Urine Low Control Lot number: E59399 Manufacturer expiration date: 2027-02-28 Open date/amended expiration date: not documented 2. Review of manufacturer instructions for "6-Acetylmorphine Urine Calibrator", "Fentanyl Urine Calibrator 1" and "Multi-drug Calibrators", "6-Acetylmorphine Urine Control Set", and "Fentanyl Urine Control Set" (no document numbers/dates available) revealed: "The opened bottles are stable for 60 days or the printed expiration date, whichever comes first." 3. In an interview on 07/22/2026 at 1130 hours in the laboratory, Testing Person number 1 (as indicated on submitted Form CMS 209), after reviewing the unlabeled reagents and manufacturer instructions, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of submitted test menu, laboratory's policies/procedures, test verification studies and staff interview, the laboratory failed to ensure verification study's precision raw data was evaluated for one of one testing platforms used by the laboratory, Toxicology Screen. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory performed Toxicology Screen using the Pictus 500 (P500) Diatron analyzer. 2. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place defining requirements for verification study's components or their evaluation for moderate complexity testing platforms. 3. Review of laboratory's verification studies revealed the laboratory failed to document evaluation of verification study's precision raw data for its Toxicology Screen P500 testing platform. 4. In an interview on 07/22/2026 at 1315 hours in the office, the laboratory's Technical Consultant confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Review of manufacturer instructions, laboratory's maintenance records from January through June 2026 and staff interview, the laboratory failed to ensure complete maintenance was documented for one of one toxicology analyzer in use, the Pictus 500 (P500) Diatron analyzer. Findings included: 1. Review of manufacturer instructions in the "P500 Instalation and User Manual" (Version B) revealed: "Daily, weekly and monthly maintenance tasks Daily - Inspect Probe Tip - Place fresh control or serum at ISE prime position - Refill system wash bottle - Empty Waste bottle - Perform System Flush - Perform Cuvette Water Blank Weekly - Perform manual tip cleaning - Check and replace the diluents and cleaning solutions at reagent tray as necessary - Create Service Backup - Perform intensive cuvette cleaning Monthly - Perform Photometer Calibration - Perform Washer Volume Calibration - Clean System bottles - Perform intensive washer cleaning" 2. Review of laboratory's maintenance records from January through June 2026 for the P500 Diatron analyzer revealed the laboratory only had documentation of the Monthly Photometer Calibration, no other maintenance was documented. 3. In an interview on 07/22/2026 at 1230 hours in the office, the laboratory's Technical Consultant confirmed the findings.
D5781	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, random quality control (QC) records from June 2026, corrective action records and staff interview, the laboratory failed to document corrective actions for failed/abnormal QC results for nine of nine instances corrective action documentation were required. Findings included: 1. Review of laboratories policy "SOP 12: Nonconformance and Corrective Action" (effective 10/03/2025) revealed: "Technical supervisor: Investigates nonconformance and develops corrective actions. Verifies resolution effectiveness. General supervisor: Assists in investigations and monitors staff compliance with corrective actions." And, "Identify nonconformances, such as: - QC results outside acceptable ranges ... Quality control: - Verify nonconformance documentation completeness weekly. - Confirm corrective action effectiveness monthly via KPI monitoring." The policy did not address responsibilities of Technical Consultant, a position required for moderate complexity testing. 2. Review of laboratory's random QC records for June 2026 revealed the following QC exclusion flags for which there was no documentation of corrective action: QC: 6-Acetylmorphine (6-AM) Negative Control Date: Time: Exclusion flag: 06/01/2026 05:16PM low 06/03/2026 11:15AM Failed Reading 06/03/2026 11:16AM Failed Reading 06/10/2026 12:37PM high QC: 6-Acetylmorphine (6-AM) Positive Control Date: Time: Exclusion flag: 06/01/2026 05:16PM Failed Reading 06/05/2026 11:16AM Failed Reading 06/05/2026 01:46PM Failed Reading 06/12/2026 12:09PM high QC: Amphetamine (AMP) Negative Control Date: Time: Exclusion flag: 06/17/2026 12:04PM low 3. Review of corrective action documentation revealed there was no specific corrective action documented for the above QC Exclusion flags/nonconformance, and no documentation of weekly verification of nonconformance documentation completeness, as per policy. 4. In an interview on 07/22/2026 at 1200 hours in the office, the laboratory's Technical Consultant confirmed the findings.
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's observations, review of submitted test menu, laboratory's policies/procedures, test verification studies, quality control and corrective action records, analyzer user manual and maintenance records, and staff interview, the laboratory

	failed to ensure its quality assurance protocols identified and corrected issues in analytic systems for one of one test performed by the laboratory, Toxicology Screen. Refer to D5417, D5421, D5427, D5429 and D5781.
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 surveyor's observations, review of submitted test menu, laboratory's policies /procedures, preanalytic test records, test verification studies, quality control and corrective action records, analyzer user manual and maintenance records, and staff interview, the laboratory director failed to provide overall management of the laboratory for one of one test performed by the laboratory, Toxicology Screen. Findings included: 1. The laboratory director failed to ensure overall quality of preanalytic and analytic systems was maintained to ensure quality laboratory services. Refer to D6007. 2. The laboratory director failed to ensure test system verification studies were complete. Refer to D6013. 3. The laboratory director failed to ensure laboratory's quality assurance identified and corrected issues in preanalytic and analytic systems. Refer to D6020.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) 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 surveyor's observations, review of submitted test menu, laboratory's policies /procedures, preanalytic test records, quality control and corrective action records, analyzer user manual and maintenance records, and staff interview, the laboratory director failed to ensure overall quality of preanalytic and analytic systems was maintained to ensure quality laboratory services for one of one test performed by the laboratory, Toxicology Screen. Refer to D5311, D5417, D5429 and D5781.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of submitted test menu, laboratory's policies/procedures, test

	verification studies and staff interview the laboratory director failed to ensure test system verification studies were complete for one of one test performed by the laboratory, Toxicology Screen. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 surveyor's observations, review of submitted test menu, laboratory's policies /procedures, test verification studies, specimen transport logs, quality control and corrective action records, analyzer user manual and maintenance records, and staff interview, the laboratory director failed to ensure laboratory's quality assurance was maintained. Refer to D5391 and D5791.