Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2145794	04/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Legacy Trail Surgery Center Llc	7211 Preston Rd Suite 2100, Plano, 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.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: I. Based on review of verification studies for the i-STAT analyzer, laboratory policies, laboratory records, and confirmed in interview, the laboratory failed to ensure the reference range (normal range) for seven of seven chemistry analytes and one of one endocrinology analytes were verified by the laboratory's studies in 2022 (June) for one of one i-STAT analyzer. Findings included: 1. According to verification studies, the laboratory added the i-STAT analyzer (serial number 317576) to their test menu on 06/2022 using the Beta-hCG cartridge for endocrinology testing and the CG8+ cartridge for blood gases. The analyte tested on the Beta-hCG cartridge included: Beta-Human Chorionic Gonadotropin. The analytes tested on the CG8+ cartridge included: Na (sodium), K (potassium), iCa (ionized calcium), Glu (glucose), pH, PO2 (oxygen partial pressure), PCO2 (carbon dioxide patrial pressure). Further review of the verification studies for the i-STAT revealed the laboratory did NOT perform a reference range study as required. 2. Review of the laboratory's policy titled "Validation/Verification of Test System Performance" revealed "Policy A. Prior to reporting patient test results, the laboratory will verify and establish the performance

characteristics for each method as defined by the Clinical Laboratory Improvement Act of 1988 (CUA) Regulation 493.1253(2). For FDA approved testing the following method evaluation/validations will be performed: Accuracy Precision Reportable Range Reference Interval ... B. Prior to reporting any patient test results, the laboratory will document the validation plan using Laboratory Validation Plan Template." Review of the laboratory's policy titled "CP 5.65 Abbot i-STAT" revealed: "Procedure H Accessing Results From i-STAT Meters ... Reference Range Test Low High Na 134 146 K 3.5 5 Glucose 70 106 iCa 1.12 1.32 pH 7.35 7.45 pCO2 35 48 pO2 83 108 B-hCG 0 5" The laboratory was asked to provide the studies used to obtain the reference ranges. None were provided. 3. Review of laboratory records revealed an annual test volume of 33 B-hCG tests and 56 CG8+ tests performed on the i-STAT analyzer. 4. During an interview on 04/23/2024 at 1:06 pm, laboratory representatives confirmed the laboratory failed to perform reference range verification studies. II. Based on review of laboratory policies, verification studies for the i-STAT analyzer, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable ranges for six of six chemistry analytes and one of one endocrinology analytes were verified by the laboratory's studies in 2022 (June) for one of one i-STAT analyzer. Findings included: 1. Review of the laboratory's policy titled "Validation/Verification of Test System Performance" revealed "Policy A. Prior to reporting patient test results, the laboratory will verify and establish the performance characteristics for each method as defined by the Clinical Laboratory Improvement Act of 1988 (CUA) Regulation 493.1253(2). For FDA approved testing the following method evaluation/validations will be performed: Accuracy Precision Reportable Range Reference Interval ... B. Prior to reporting any patient test results, the laboratory will document the validation plan using Laboratory Validation Plan Template." 2. According to verification studies, the laboratory added the i-STAT analyzer (serial number 317576) to their test menu on 06/2022 using the Beta-hCG cartridge for endocrinology testing and the CG8+ cartridge for blood gases. The analyte tested on the Beta-hCG cartridge included: Beta-Human Chorionic Gonadotropin. The analytes tested on the CG8+ cartridge included: Na (sodium), K (potassium), iCa (ionized calcium), Glu (glucose), pH, PO2 (oxygen partial pressure), PCO2 (carbon dioxide patrial pressure). 3. Further review of the verification studies for i-STAT analyzer revealed the laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for chemistry analytes as required by 493.1253 as follows: Reportable range from verification study: Na: 100-176 Laboratory reportable range: Na: 100-180 The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study: K: 2.3-7.8 Laboratory reportable range: K: 2.0-9.0 The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study: Glucose: 30-565 Laboratory reportable range: Glucose: 20-700 The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study: pH: 6.583-7.926 Laboratory reportable range: pH: 6.5* -8.20* The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study: pCO2: 18.3-84.4 Laboratory reportable range: pCO2: 5*-130* The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study: pO2: 59-380 Laboratory reportable range: pO2: 5*-800* The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study: B-hCG: 2.8-1945.3 Laboratory reportable range: B-hCG: NA The laboratory's established reportable range did not coincide with the reportable range

	obtained in the verification studies. 4. During an interview on 04/23/2024 at 12:40 pm, laboratory representatives confirmed the above findings. Word Key: NA= Not Applicable
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the B-hCG (Beta-Human Chorionic Gonadotropin) cartridge for four of four days in 2022 and six of six days in 2023. Findings included: 1. Review of laboratory policy "CP 5.65 Abbott i-STAT" revealed: "Quality Control (QC) Specifications Monthly Liquid QC Materials B-hCG: Level 1 and Level 3 Controls ... Frequency Performed monthly on each cartridge type" The laboratory failed to develop an IQCP (Individualized Quality Control Plan) to support its reduction in frequency to "monthly". 2. Review of QC and patient records in June 2022 through November 2023, revealed the following dates two levels of QC was not performed and patients were analyzed for the B-hCG analyte: i-STAT Serial #317576 07/13/2022 Patient ID: 00006204 08/11/2022 Patient ID: 00006731 08/12/2022 Patient ID: 00006772 08/29/2022 Patient ID: 00006864 No documentation of QC being performed prior to the above dates 08/03/2023 Patient ID: 00008517 08/07 /2023 Patient ID: 00008580 08/21/2023 Patient ID: 00008724 08/23/2023 Patient ID: 00008712 QC last performed on 08/02/2023 11/13/2023 Patient ID: 00005319 11/15 /2023 Patient ID: 00005757 QC last performed on 11/01/2023 3. During an interview on 04/23/2024 at 12:38 pm, the laboratory representatives confirmed the above findings.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Center for Medicare and Medicaid Services (CMS) 209 form, quality control (QC) records, and confirmed in interview, the laboratory failed, over time, to rotate i-Stat analyzer control material testing among all testing persons (TP) for 12 of 13 testing persons. Findings included: 1. Review of the laboratory's policy titled "Validation/Verification of Test System Performance" revealed: "POLICY STATEMENT: Children's Health System of Texas (CHST) and its affiliates (collectively, Children's Health) will provide instructions on the operation, maintenance, quality control (QC) testing, and troubleshooting of the

	Abbott i-STAT (i-STAT) meter. This policy is applicable to clinical employees who are trained and competent in POCT for the i-STAT meter ... PROCEDURE: CG8, bHCG cartridges: These cartridges are FDA approved and moderate complex. Upon training and successful passing of the i- STAT competency, only the following clinical employees shall operate an i-STAT meter: Registered nurses Respiratory care practitioners Physician assistants Medical staff members Perfusionists Radiology technologists Paramedics in Emergency Transport Point of Care Testing (POCT) Department employees Other staff, upon direct approval from the Division Director of Pathology" 2. Review of the CMS 209 form identified 13 testing personnel that performed testing on the i-Stat analyzer. 3. Review of i-STAT analyzer quality control (QC) records from 09/2022 through 02/2024 for the B-hCG cartridge and 03/2022 through 02/2024 for the CG8+ cartridge revealed QC was analyzed 18 times (every 30 days) for the B-hCG catridge and 24 times (every 30 days) for the CG8+ cartridge. QC monthly logs revealed documentation of TP-1 name, as the one who performed QC testing for all 42 times. 4. During an interview on 04/23/2024 at 1:48 pm, laboratory representatives after a review of records confirmed the laboratory failed, over time, to rotate i-Stat analyzer control material testing among all testing persons. Word Key: B-hCG- Beta-Human Chorionic Gonadotropin
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 laboratory policy, Abbott i-STAT quality control (QC) records, and staff interview, it was revealed the laboratory failed to verify the criteria for acceptability of all control materials for ten of ten Tri-Control lots used in 2022, 2023 and 2024 and four of four B-hCG control lots used in 2022, 2023, and 2024. Findings included: 1. Review of the laboratory's policy " POCT 1.11 Quality Control and Quality Assurance for POCT POCT 1.11 Quality Control and Quality Assurance for POCT" revealed: "Procedure A Control Lot Validation I- STAT Control Validations Using four i-STAT meters, run the new controls as appropriate for the EG7, EC8, Creatinine, CG4, and ACT cartridges at least three times ... STEP 1 ACTION Verify that all results are within the manufacturer's specified, acceptable range IF If the result value does not meet the acceptable range provided THEN Repeat the unacceptable control IF The repeated results are acceptable THEN Document on the validation sheet that QC was repeated and was acceptable IF The repeated results are not acceptable THEN Consult with the POCT Manager and CC STEP 2 ACTION Enter the results into the appropriate control lot validation spreadsheet The mean is calculated automatically IF The calculated mean result does not meet criteria THEN

	Consult with the POCT Manager and CC IF The calculated mean result does meet criteria THEN Use the specified manufacturer's mean as the acceptable mean STEP 3 ACTION Determine the acceptable range for the control by using the lab's measured mean with the manufacturer's standard deviation (SD). STEP 4 ACTION Record results on the Control Validation Sheet STEP 5 ACTION Submit the completed sheet to the POCT Manager for review and approval" 2. Review of the Tri- Control quality control logs from 2022, 2023 and 2024 revealed the following quality control lot numbers were placed into service and the laboratory failed to cross-check the new quality control lot against the old quality control lot for levels 1 and 3: Level 1; Lot # 301145; expiration date 01/31/2023 Level 3; Lot # 321145; expiration date 01/31 /2023 Level 3; Lot # 321141; expiration date 09/30/2022 Level 1; Lot # 301151; expiration date 07/31/2023 Level 3; Lot # 321146; expiration date 02/28/2023 Level 1; Lot # 301154; expiration date 10/31/2023 Level 3; Lot # 301154; expiration date 10 /31/2023 Level 3; Lot # 321154; expiration date 10/31/2023 Level 1; Lot # 301161; expiration date 05/31/2024 Level 3; Lot # 321161; expiration date 05/31/2024 Review of the B-hCG control quality control logs from 2022, 2023 and 2024 revealed the following quality control lot numbers were placed into service and the laboratory failed to cross-check the new quality control lot against the old quality control lot for levels 1 and 3: Level 1; Lot # 351159; expiration date 03/31/2024 Level 3; Lot # 371155; expiration date 01/30/2023 Level 1; Lot # 351163; expiration date 07/31 /2024 Level 3; Lot # 371163; expiration date 07/31/2024 3. During an interview on 04 /23/2024 at 1:48 pm, the laboratory representatives confirmed the laboratory failed to verify the criteria for acceptability of the control material. Word Key: B-hCG- Beta-Human Chorionic Gonadotropin
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing on the i-Stat analyzer using the CG8+ cartridge for four of four days in 2023. Findings included: 1. Review of laboratory policy "CP 5.65 Abbott i-STAT" revealed: "Quality Control (QC) Specifications Monthly Liquid QC Materials Blood Gas: Level 1 and Level 3 Controls ... Frequency Performed monthly on each cartridge type" The laboratory failed to develop an IQCP (Individualized Quality Control Plan) to support its reduction in frequency to "monthly". 2. Review of QC and patient records in June 2023 through December 2023, revealed the following dates QC was not performed each 8 hours of testing using a combination of control materials that include both low and high values on each day of patient testing and patients were analyzed for blood gases: i-STAT Serial #317576 06/01/2023 Patient ID: 00007979 QC last performed on 05/31/2023 09/13 /2023 Patient ID: 00003933 QC last performed on 09/07/2023 11/15/2023 Patient ID: 00005757 QC last performed on 11/01/2023 12/18/2023 Patient ID: 00009328 QC last performed on 12/01/2023 3. During an interview on 04/23/2024 at 12:38 pm, the laboratory representatives confirmed the above findings.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) 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 review of laboratory policies, i-STAT verification studies, and confirmed in interview, the laboratory director failed to ensure the reportable range and precision studies were acceptable for one of one i-STAT analyzers prior to reporting patient test results in 2022. Findings included: 1. Review of the laboratory's policy "Validation/ Verification of Test Systems Performance" revealed: Policy A. Prior to reporting patient test results, the laboratory will verify and establish the performance characteristics for each method as defined by the Clinical Laboratory Improvement Act of 1988 (CLIA)Regulation 493.1253(2). For FDA approved testing the following method evaluation/validations will be performed: Accuracy Precision Reportable Range Reference Interval ... F. Each test method is reviewed, evaluated, and approved by the Medical Director or Clinical Consultant (CC) before any patient test results are reported." 2. Review of the laboratory's verification studies for the i-STAT analyzer (Serial #317576) for testing performed on the CG8+ (blood gas) and B-hCG cartridges revealed the studies for reportable range and precision were approved by the clinical consultant and NOT the laboratory director. 3. During an interview on 04 /23/2024 at 12:50 pm, the laboratory representatives confirmed the laboratory director failed to approve the reportable range and precision studies prior to reporting patient test results on the CG8+ and B-hCG cartridges. Word Key: B-hCG- Beta-Human Chorionic Gonadotropin
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of personnel records from September 2022 through the day of the survey, April 23, 2024, and staff interview, the laboratory's testing personnel competency assessments failed to include monitoring recording and reporting of test results for 10 of 13 testing personnel. Findings included: 1. Review of testing personnel (TP) files #2, #3, #4, #5, #6, #7, #8, #10, 11, and #12 revealed that monitoring recording and reporting of test results was absent from the employee competency assessments performed on the following dates: TP Date(s) #2 01/2023, 01 /2024 #3 01/2023, 01/2024 #4 01/2024 #5 01/2023, 01/2024 #6 09/2022, 01/2023, 01 /2024 #7 01/2023, 01/2024 #8 09/2023, 01/2024 #10 08/2022 #11 10/2022, 01/2023 #12 01/2024 2. The laboratory was asked to provide documentation of monitoring

	recording and reporting of test results as part of the competency assessments. No documentation was provided. 3. During an interview on 04/23/2024 at 10:40 am, the laboratory representatives confirmed the above findings.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 personnel records from September 2022 through the day of the survey, April 23, 2024, and staff interview, the laboratory's testing personnel competency assessments failed to include review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for 10 of 13 testing personnel. Findings included: 1. Review of testing personnel (TP) files #2, #3, #4, #5, #6, #7, #8, #10, 11, and #12 revealed that review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records was absent from the employee competency assessments performed on the following dates: TP Date(s) #2 01/2023, 01 /2024 #3 01/2023, 01/2024 #4 01/2024 #5 01/2023, 01/2024 #6 09/2022, 01/2023, 01 /2024 #7 01/2023, 01/2024 #8 09/2023, 01/2024 #10 08/2022 #11 10/2022, 01/2023 #12 01/2024 2. The laboratory was asked to provide documentation of review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records as part of the competency assessments. No documentation was provided. 3. During an interview on 04/23/2024 at 10:40 am, the laboratory representatives confirmed the above findings.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of personnel records from September 2022 through the day of the survey, April 23, 2024, and staff interview, the laboratory's testing personnel competency assessments failed to include the direct observation of instrument maintenance and function checks for 10 of 13 testing personnel. Findings included: 1. Review of testing personnel (TP) files #2, #3, #4, #5, #6, #7, #8, #10, 11, and #12 revealed that direct observation of instrument maintenance and function checks was absent from the employee competency assessments performed on the following dates: TP Date(s) #2 01/2023, 01/2024 #3 01/2023, 01/2024 #4 01/2024 #5 01/2023, 01 /2024 #6 09/2022, 01/2023, 01/2024 #7 01/2023, 01/2024 #8 09/2023, 01/2024 #10 08 /2022 #11 10/2022, 01/2023 #12 01/2024 2. The laboratory was asked to provide documentation of direct observation of instrument maintenance and function checks as part of the competency assessments. No documentation was provided. 3. During an interview on 04/23/2024 at 10:40 am, the laboratory representatives confirmed the above findings.