

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0698063	(X3) Date Survey Completed 11/08/2022
Name of Provider or Supplier Baylor St Luke's Medical Group	Street Address, City, State 310 Gaslight Boulevard, Lufkin, 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	
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, American Proficiency Institute (API) Proficiency Testing (PT) 2022 records, and staff interview, the laboratory director and testing person failed to attest to the routine integration of proficiency samples into the patient workload for 2 of 2 Hematology proficiency testing events in 2022. Findings Included: 1. Review of the CMS 209 form revealed 1 Testing Person (TP-1) performing moderate complexity hematology testing. 2. Review of API instructions stated the following: "Attestation statement Signatures required- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of the laboratory's API proficiency testing 2022 records (Hematology 1st and 2nd Events), revealed the laboratory director or designee and testing person, failed to sign the attestation statement for the following events: 2022 API Hematology 1st Event The Laboratory Director and TP-1 failed to attest to the routine integration of proficiency samples into the patient workload. 2022 API Hematology 2nd Event The Laboratory Director and TP-1 failed to attest to the routine integration of proficiency samples into the patient workload. 4. During an interview on 11/08/2022 at 10:16 a.m., in the facility conference room, TP-1 confirmed the above findings. II. Based on American Proficiency Institute (API) Proficiency Testing (PT) 2022 records, and staff interview,</p>

the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 2 Chemistry proficiency testing events in 2022. Findings Included: 1. Review of the CMS 209 form revealed 1 Testing Person (TP-1) performing moderate complexity chemistry testing. 2. Review of API instructions stated the following: " Attestation statement Signatures required- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of the laboratory's API proficiency testing 2022 records (Chemistry 1st and 2nd Events), revealed the laboratory director or designee and testing person, failed to sign the attestation statement for the following: 2021 API Chemistry 2nd Event The Laboratory Director and TP-1 failed to attest to the routine integration of proficiency samples into the patient workload. 2021 API Chemistry 3rd Event The Laboratory Director and TP-1 failed to attest to the routine integration of proficiency samples into the patient workload. 4. During an interview on 11/08/2022 at 10:16 a.m., in the facility conference room, TP-1 confirmed the above findings.

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:

I. Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in staff interview, the laboratory failed to ensure the acceptable laboratory temperature range was within manufacturer's specifications for the Bio Rad Liquicheck Immunoassay Plus Control for 3 of 3 months randomly reviewed in 2022 (08/2022-10/2022). Findings Included: 1. During a tour of the facility on 11/07/2022 at 09:30 a.m., the surveyor observed 2 boxes containing Bio Rad Liquicheck Immunoassay Plus Control (Lot Number: 85320) in the freezer. 2. Review of manufacturer's instructions for the Bio Rad Liquicheck Immunoassay Plus Control (Lot Number: 85310), revealed the following: "Procedure: Before sampling, allow this product to reach room temperature (18-25 C). If the product has been stored frozen, allow it to stand at room temperature (18-25 C) until it is completely thawed." 3. Random review of laboratory environmental logs (08/2022-10/2022) revealed the following acceptable room temperature range: 18-30 C The laboratory failed to ensure the acceptable laboratory temperature range was within manufacturer's specifications for the Bio Rad Liquicheck Immunoassay Plus Control for 3 of 3 months randomly reviewed in 2022. 4. During an interview on 11/08/2022 at 10:20 a.m., in the facility conference room, TP-1 confirmed the above findings. II. Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in staff interview, the laboratory failed to ensure the acceptable laboratory temperature range was within manufacturer's specifications for the Eight Check Hematology Control for 3 of 3 months randomly reviewed in 2022 (08/2022 - 10/2022). Findings Included: 1. During a tour of the facility on 11/07/2022 at 10:30 a.m., the surveyor observed 1 container of Eight

Check Hematology Control in the refrigerator. 2. Review of manufacturer's instructions for the Eight Check Hematology Control, revealed the following: "Instructions for Use: 1. Remove vial from refrigerator and packaging. 2. Allow at least 15 minutes to warm vials to room temperature (18-25 C)" 3. Random review of laboratory environmental logs (08/2022-10/2022) revealed the following acceptable room temperature range: 18-30 C The laboratory failed to ensure the acceptable laboratory temperature range was within manufacturer's specifications for the Eight Check Hematology Control for 3 of 3 months randomly reviewed in 2022. 4. During an interview on 11/08/2022 at 10:20 a.m., in the facility conference room, TP-1 confirmed the above findings.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory policies, quality control (QC) records, patient records, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of Bio Rad Liquicheck Immunoassay Plus QC material over time on the Tosoh AIA-360 analyzer for 12 of 12 months (10/2021 through 10/2022) to ensure accurate and reliable test results. Findings Included: 1. During a tour of the facility on 11/07/2022 at 10:30 a.m., the surveyor observed a Tosoh AIA-360 (Serial Number: 879072) on the laboratory work bench. 2. Review of laboratory policies for the Tosoh AIA-360 analyzer revealed the laboratory did not have a procedure for monitoring the accuracy and precision over time to ensure accurate and reliable test results. Further review revealed the only analyte processed on the Tosoh AIA-360 was Thyroid Stimulating Hormone (TSH). 3. The laboratory was asked to provide documentation of monitoring QC over time for analytes tested on the Tosoh AIA-360, using the Bio Rad Immunoassay Plus QC material. No documentation was provided. The laboratory failed to monitor the accuracy and precision of Bio Rad Liquicheck Immunoassay Plus QC material over time on the Tosoh AIA-360 analyzer for 12 of 12 months (10/2021 through 10/2022) to ensure accurate and reliable test results. 4. The following is a random sampling of TSH patients performed in 2022: Patient Identification (ID): #1; #2; #3; #4; #5; #6; #7; #8; #9; #10 (See attached Patient ID chart for corresponding patients.) 5. During an interview on 11/08/2022 at 9:20 a.m., in the laboratory, TP-1 confirmed the above findings.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of laboratory documents, laboratory records, the Centers for Medicaid and Medicare (CMS) form 116, and confirmed in interview, the laboratory failed to complete a Individualized Quality Control Plan (IQCP) to include risk assessment to identify and evaluate potential failures and sources of errors in the testing process, establish a quality control plan (QAP), and a quality assessment (QA) to support a reduction of the QC frequency from every day of patient testing for the i-STAT Chem 8+ cartridge from January to October 2022. The findings include: 1. In a tour of the laboratory on 11/7/2022 at 10:10 am, the surveyor noticed a blue container next to an i-STAT machine labeled "BMP". It contained 19 i-STAT Chem 8+ cartridges out for use with the following lot and expiration date: Lot: H22216A, EXP 1/31/2021 2. Review of quality control (QC) records from January to October 2022 listed 2 levels of QC performed once a month. 3. Review of the laboratory policy titled "I-STAT Chem 8 Risk Assessment and Quality Control Plan" included a risk assessment and quality control for the test BNP and a Risk Assessment for the CHEM8+ cartridge that was not completed for all areas of potential errors. Surveyor queried testing person (TP) 1, in the conference room, if there was a completed IQCP that included a completed risk assessment, a quality control plan specific to the i-STAT Chem 8+, and a completed QA plan to monitor the effectiveness of the reduction of QC frequency from every day of patient testing to once a month and none was provided. 4. Review of laboratory testing totals provided by TP1 had the annual test volume for the i-STAT Chem 8+ cartridge at 8,064. 5. In an interview on 11/7/2022 at 11:45 hours, in the conference room, TP1 confirmed that the laboratory did not have a IQCP to support the reduction of QC frequency from every day of patient testing to one a month for the i-STAT Chem 8+ cartridges.

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 a review of laboratory documents, quality control records, patient test records, and confirmed in interview, the laboratory failed to run two levels of controls every day of patient testing for the i-STAT Chem 8+ cartridges for 11 of 11 random patients reviewed from January to October 2022. The findings include: 1. In a tour of the laboratory on 11/7/2022 at 10:10 am, the surveyor noticed a blue container next to an i-STAT machine labeled "BMP". It contained 19 i-STAT Chem 8+ cartridges out for use with the following lot and expiration date: Lot: H22216A, EXP 1/31/2021 2.

Surveyor queried on 11/7/2022 at 11:10, in the laboratory, how often QC was run for the i-STAT Chem 8+ testing. Testing person (TP) 1 stated they run it at the beginning of each month. A review of laboratory QC records titled "iSTAT CHEM 8+ Control Level 1 & 3" confirmed a QC frequency of once a month. 3. Review of laboratory testing totals provided by TP1 had the annual test volume for the i-STAT Chem 8+ cartridge at 8,064; to include the following 11 random sampling of patients tested with the iSTAT Chem 8+ cartridge on days where QC wasn't performed: January: 3 Patients QC performed and documented on 1/4/2022 Patient ID - Date of testing 10110023 -1/10/2022 1011044 -1/11/2022 1011049 -1/11/2022 May 2022: 3 Patients QC Performed and documented on 5/2/2022 Patient ID - Date of testing 10509060 -5/9/2022 10509061 -5/9/2022 10509057 -5/9/2022 August 2022: 3 Patients QC performed and documented 8/2/2022 10809035 -8/9/2022 10809037 -8/9/2022 10809041 -8/9/2022 October 2022: 2 Patients QC performed and documented 10/4/2022 1100522003 -10/5/2022 1100522013 -10/5/2022 4. In an interview on 11/7/2022 at 11:15, in the laboratory, TP1 confirmed that the laboratory did not run 2 levels of QC every day of patient testing for the i-STAT Chem 8+ cartridge.

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:
I. Based on direct observation, review of the Bio Rad Liquicheck Immunoassay Plus Control instructions for use (IFU), facility policy, and confirmed in staff interview, it was revealed the laboratory failed to establish their own control acceptable ranges for 1 of 1 test performed on the Tosoh AIA- 360 analyzer for 1 of 1 control lot reviewed in 2022. Findings Included: 1. During a tour of the facility on 11/07/2022 at 10:30 a. m., the surveyor observed a Tosoh AIA-360 (Serial Number: 879072) on the laboratory work bench. Further investigation revealed Thyroid Stimulating Hormone (TSH) was the only analyte performed on the Tosoh AIA-360 analyzer. 2. Review of Bio Rad Liquicheck Immunoassay Plus Control (Lot Number:85310) IFU, revealed the following: "Assignment of Values: It is recommended that each laboratory establish its own acceptable ranges and use those provided as guides." Further review of the IFU revealed the following value assignments for TSH: "Thyroid Stimulating Hormone (TSH) Lot Number: 85310; Expiration Date: 02/24/2024 Level 1 Range- 0.560-1.04 Level 2 Range- 4.10-7.62 Level 3 Range- 20.8-38.7" 3. Review of facility policy, "Quality Control Policy" (Reviewed by the Laboratory Director on 07/10/2019) revealed the following: "The Laboratory Director will ensure that policies and procedures are established to monitor, evaluate, and review: a. Quality Control- establish a mechanism to verify all test confirm to specified performance criteria in

the quality of laboratory services provided and to identify failures in quality. Further review of the policy revealed: "Procedure: Action- Quality Control a. Quality control material is run in each department. The control material is dependent on the instrument. b. Analytically acceptable ranges are established for the instruments." 4. Review of Bio Rad Liquicheck Immunoassay Plus control records revealed the following acceptable quality control ranges: "Thyroid Stimulating Hormone (TSH) Lot Number: 85310; Expiration Date: 02/24/2024 Level 1 Range- 0.560-1.04 Level 2 Range- 4.10-7.62 Level 3 Range- 20.8-38.7" The laboratory failed to establish their own control acceptable ranges for 1 of 1 test performed on the Tosoh AIA- 360 analyzer for 1 of 1 control lot reviewed in 2022. 5. During an interview on 11/08/2022 at 10:20 a.m., in the facility conference room, TP-1 confirmed the above findings. 45469 II. Based on a review of laboratory quality control (QC) instrument printouts, instructions for use, laboratory documents, and confirmed in an interview, the laboratory failed to have a policy in place for the establishment or verification of control ranges for 19 of 19 chemistry analytes reviewed on the Ace Axcel chemistry analyzer from January to March 2022. The findings include: 1. Review of the QC requisition report from the Ace Axcel instrument had the following acceptable ranges for QC from January to March 2022: Control 1 - Lot 1501UNCM Test - Acceptable Range CA - 8.9 - 10.1 ALT - 46 - 60 GLU - 86 - 60 BUN - 10 - 14 TBILI - 1.3 - 1.9 ALB - 2.6 - 3.2 CREAT - 1.61 - 2.01 AST - 42 - 56 NA - 129.3 - 148.7 K - 0.81 - 7.49 CL - 99.6 - 113.6 TRIG - 84 - 104 DBILI - 0.9 - 1.5 HDL - 34 - 42 ALP - 56 - 74 CHOL - 102 - 116 CO2 - 12.7 - 16.5 MG - 2.2 - 2.8 TP - 4.3 -4.9 Control 2 - Lot 1166UECM Test - Acceptable Range CA - 11.5 - 13.1 ALT - 121 - 157 GLU - 270 - 308 BUN - 43 -57 TBILI - 4.6 -6.0 ALB - 4.1 - 5.1 CREAT - 6.71 - 8.19 AST - 185 - 243 NA - 114.6 - 131.4 K - 7.33 - 7.99 CL - 77.0 - 87.0 TRIG - 159 - 197 DBILI - 2.5 -3.1 HDL - 63 - 77 ALP - 327 - 433 CHOL - 177 -203 CO2 - 25.7 - 33.7 MG - 4.4 - 5.4 TP - 7.3 - 8.3 A review of the QC instructions for use included assayed ranges different than the stated ranges on the Ace Excel chemistry analyzer used for daily acceptability. Surveyor queried testing personnel (TP) 1 for the laboratory policy for the establishment of QC ranges for the Ace Excel chemistry analyzer, and none was provided. 2. Review of the CMS form 116 had a total annual test volume for the specialty chemistry listed at 27,972. 3. In an interview on 11/8/2022 at 14:48, in the conference room, TP 1 confirmed the laboratory did not have a policy for the establishment of QC ranges for the Ace Axcel chemistry analyzer. Key: CA - Calcium ALT - Alanine transaminase GLU - Glucose BUN - Blood Urea Nitrogen TBILI - Total Bilirubin ALB - Albumin CREAT - Creatinine AST - Aspartate transaminase NA - Sodium K - Potassium CL - Chloride TRIG - Triglycerides DBILI - Direct Bilirubin HDL - High Density Lipoproteins ALP - Alkaline Phosphatase CHOL - Cholesterol CO2 - Carbon dioxide MG - Magnesium TP - Total Protein

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the submitted Centers for Medicare and Medicaid (CMS) 116 Application, random review of final patient reports and confirmed in staff interview, it was revealed the laboratory failed to ensure the correct physical address for all tests performed was documented on the final patient reports for 10 of 10 patients randomly reviewed in November 2022. Findings Included: 1. Review of CMS 116 application submitted at the time of survey, revealed the following address for the laboratory: "310 Gaslight Blvd Lufkin, TX 75904" 2. Random review of final patient reports revealed the following 10 of 10 reports in November 2022 that did not include the correct physical address of the laboratory: Patient Identification (ID): #1; #2; #3; #4; #5; #6; #7; #8; #9; #10 (See attached Patient ID chart for corresponding patients.) 3. During an interview on 11/07/2022 at 3:20 p.m., in the facility conference room, TP-1 confirmed the above findings.