| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2015924 | 05/23/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Baylor Scott & White Surgical Hospital | 3601 N Calais St, Sherman, 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 |
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| **D0000** | Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **D2020** | BACTERIOLOGY<br>CFR(s): 493.823(a)<br><br>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CMS form 155, American Proficiency Institute (API) proficiency testing records (Microbiology 2017 1st. 2nd, and 3rd Event, Microbiology 2018 1st. 2nd, and 3rd Event, Microbiology 2019 1st Event) and staff interview, it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for 1 of 7 events for the specialty of Bacteriology. Findings included: 1. Review of the CMS form 155 revealed the following unsatisfactory score: 2018 Microbiology - 1st Event laboratory received an unsatisfactory score of 50% for Bacteriology. 2. Review of the laboratory API proficiency testing records (Microbiology 2017 1st. 2nd, and 3rd Event, Microbiology 2018 1st. 2nd, and 3rd Event, Microbiology 2019 1st Event) revealed the following scores: Microbiology 2018 1st Event: Sample MRS-01 |

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| | Acceptable Sample MRS-02 Unacceptable Overall score 50% 3. The above findings were confirmed by the technical consultant on 05/22/2019 at 1100 hours in the conference room. |
| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CMS form 155, American Proficiency Institute (API) proficiency testing records (Chemistry Core 2017 2nd and 3rd Event, Chemistry Core 2018 1st. 2nd, and 3rd Event, Chemistry Core 2019 1st Event) and staff interview, it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for the sodium analyte for 1 of 6 testing events (2018 Chemistry API 1st Event). Findings included: 1. Review of the CMS form 155 revealed the following unsatisfactory score: 2018 Chemistry API - 1st Event laboratory received an unsatisfactory score of 20% for the sodium analyte. 2. Review of the API 2018 Chemistry Core 1ST Event performance summary report revealed the following: Sodium - Score 20% The laboratory failed to attain an acceptable score of at least 80% for the Sodium analyte. 3. The above findings were confirmed by the technical consultant on 05/22/2019 at 1100 hours in the conference room. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of the laboratory's Individualized Quality Control Plan (IQCP) for the modification of the frequency of quality control (QC) testing performed for the Abbott i-STAT chemistry analyzer, i-STAT QC records, and staff interview, it was revealed the laboratory failed to provide documentation of a complete IQCP for the i-STAT. Findings included: 1. During a tour of the laboratory on 05/22/2019 at 1100 hours, an Abbott i-STAT chemistry analyzer (Serial number 341679) was observed. The analyzer was used to test pH, PO2, PCO2, Troponin and Lactate analytes. 2. Review of the laboratory policy titled "IQCP" (Effective date October 2018) stated the following: " The laboratory has identified the following tests that will utilize the IQCP plan: i-STAT G4+ ABG+Lactate/LAC - QC per lot/monthly and 6- month calibration verification: Testing of two levels of external i-STAT control solution per each lot/shipment before or concurrently with placing these materials into service. Thereafter testing with two levels of external quality control solution per each lot/shipment and/or every 31 days. i-STAT Cardiac Troponin I/cTnl - QC per lot |

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| | /monthly and 6- month calibration verification: Testing of two levels of external cTnl control per each lot/shipment before or concurrently with placing these materials into service. Thereafter testing with two levels of external quality control per each lot /shipment and/or every 31 days." 3. Review of i-STAT QC records from 10/03/2018 through 05/20/2019 revealed the following dates when QC was performed: 10/03 /2018 10/22/2018 11/15/2018 12/10/2018 01/02/2019 01/23/2019 02/01/2019 02/25 /2019 03/27/2019 04/22/2019 05/14/2019 05/20/2019 4. During an interview on 05/22 /2019 at 1330 hours in the conference room, the technical consultant was asked to provide documentation of control material raw data for 31 consecutive days as part of their IQCP. The technical consultant stated that the laboratory director evaluated the frequency of control runs based on the new lot/shipment and monthly QC performance. The laboratory failed to provide documentation of a complete IQCP for the i-STAT allowing controls to be run less frequently. This confirmed the above findings. |