| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0471956 | 10/14/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mercy Hospital Healdton, Inc | 3462 Hospital Rd, Healdton, OK | |

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** | The recertification survey was performed on 10/12,13,14/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, hospital administrator, administrative assistant, technical consultant from Mercy Hospital Tishomingo, technical consultant #1, testing person #4, and testing person #6 during an exit conference performed at the conclusion of the survey. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the laboratory failed to review and evaluate proficiency testing results for 1 of 13 events. Findings include: (1) On 10/12/2020, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following failure:Second 2018 Chemistry Miscellaneous Event (i) Second 2020 Hematology/Coagulation Event - The laboratory failed the results for 1 of 2 samples (US-06). There was no evidence corrective action had been taken for the failed result. (2) The surveyor reviewed the records with technical consultant #1 and asked if corrective action had been taken and documented for the failure. Technical consultant #1 stated to the surveyor on 10/12 /2020 at 3:30 pm there was no documentation to prove corrective action had been taken for the failed result. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, procedure manual, and interview with technical consultant #1 and the technical consultant from Mercy Hospital Tishomingo, the laboratory failed to demonstrate precision and ensure the verified reportable ranges were used by the laboratory for 1 of 1 new test methods. Findings include: (1) On 10/12/2020 at 10:30 am, technical consultant #1 stated to the surveyor the laboratory began performing pH, pCO2, and pO2 testing using the EG6+ cartridge and the iSTAT 1 analyzer on 03/13/2020; (2) On 10/13/2020, the surveyor reviewed the performance specification records for the new test method, and was not able to find evidence that precision had been demonstrated for each analyte; (3) In addition, the surveyor reviewed the performance specification records and the procedure titled, "Procedure Manual for the i-STAT System" under the heading, "Reference Ranges, Reportable Ranges, and Test Unit Conversions". Technical consultant #1 stated to the surveyor on 10/13/2020 at 1:00 pm that the reportable ranges in the procedure manual were being used by the laboratory. The surveyor identified the reportable ranges that had been demonstrated by the laboratory did not match the reportable ranges listed in the procedure manual as follows: (a) pH - The laboratory had demonstrated a reportable range of 6.524-7.883 and the reportable range listed in the procedure manual was 6.5-8.2; (b) pCO2 - The laboratory had demonstrated a reportable range of 19.1-93.2 and the reportable range listed in the procedure manual was 5-130; (c) pO2 - The laboratory had demonstrated a reportable range of 58-429 and the reportable range listed in the procedure manual was 5-800. (4) The surveyor reviewed the records with the technical consultant from Mercy Hospital Tishomingo, who stated to the surveyor on 10/13/2020 at 2:30 pm precision had not been demonstrated by the laboratory, and the procedure manual did not reflect the reportable ranges that had been demonstrated by the laboratory. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1 and the technical consultant from Mercy Hospital Tishomingo, the laboratory failed to have |

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| | control procedures that monitored the accuracy and precision of the complete analytic process for coagulation testing for 2 of 2 lot numbers. Findings include: (1) On 10/12 /2020 at 09:45 am, technical consultant #1 stated the following to the surveyor: (a) PT /INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Stago Satellite analyzer; (b) Two levels of STA Coag Control quality control (QC) materials (normal-N Plus and abnormal-ABN Plus) were performed each eight hours of patient testing; (c) Established ranges were used for determining acceptability of QC results. (2) On 10/13 /2020, the surveyor reviewed coagulation records and identified STA Coag Control N Plus (normal level) and STA Coag Control ABN Plus (abnormal level) control materials (lot #256057) were put into use on 07/02/2020. The documentation showed the following ranges had been established by the laboratory: (a) PT Normal Level - A 2 standard deviation (SD) range of 13.5-14.5; (b) PT Abnormal Level - A 2 SD range of 25.1-29.1; (c) PTT Normal Level - A 2 SD range of 32.1-36.1; (d) PTT Abnormal Level - A 2 SD range of 71-84.6. (3) The surveyor reviewed QC records, which consisted of laboratory worksheets utilized while establishing QC ranges, and Levey-Jennings graphs and cumulative data generated from the LIS (laboratory information system) from 07/02/2020 through 10/13/2020. The documentation showed the QC lot number had not been updated in the LIS (it reflected the previous lot number of 254755), and the laboratory established ranges had not put into use. The ranges utilized were as follows: (a) PT Normal Level - A 2 SD range of 12.2-16.2 had been used from 07/02/2020 through 10/13/2020; (b) PT Abnormal Level - A 2 SD range of 24-30 had been used from 07/02/2020 through 07/31/2020; and a 2 SD range of 23.6-30.6 had been used from 08/01/2020 though 10/13/2020; (c) PTT Normal Level - A 2 SD range of 34.1-38.9 had been used from 07/02/2020 through 10/13/2020; (d) PTT Abnormal Level - A 2 SD range of 72.4-83 had been used from 07/02/2020 through 10 /13/2020. (4) The surveyor reviewed the records with the technical consultant from Mercy Hospital Tishomingo, who stated the following on 10/13/2020 at 1:00 pm: (a) The laboratory had not updated the LIS with the new QC lot number when the materials had been put into use on 07/02/2020; (b) The laboratory had carried over the 2 SD ranges that had been used for the previous lot number of QC for PT Normal level, PTT Normal level, and PTT abnormal level instead of entering their established ranges; (c) The 2 SD range that had been utilized for PT Abnormal level did not correlate to the range for the previous QC lot number or the laboratory established ranges, and it could not be determined where the ranges originated. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 2 of 13 events. Findings include: (1) On 10/12/2020, the surveyor reviewed 2019 and 2020 proficiency testing events, and identified for 2 of 13 events, |

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| | the attestation statements had been signed approximately 1 month after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Second 2019 - Hematology/Coagulation Event - The sample testing had been completed on 03 /27/2020, and the attestation statement had not been signed by the laboratory director /designee until 04/21/2020 (the graded evaluation had been received on 04/16/2020); (b) First 2020 Hematology/Coagulation Event - The sample testing had been completed on 07/22/2019, and the attestation statement had not been signed by the laboratory director/designee until 08/30/2019 (the graded evaluation had been received on 08/15/2019). (2) The surveyor reviewed the findings with technical consultant #1, who stated on 10/12/2020 at 3:40 pm the attestations had been signed approximately 1 month after the proficiency samples had been tested. The surveyor explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens. |