| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0660752 | 06/14/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Haskell Memorial Hospital | 1 North Avenue N, Haskell, 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** | The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Observations, review of quality control records, patient test records and interview of facility personnel found that the laboratory failed to test at least two levels of quality control material at least once each month for all analytes tested on the two Alere Triage meters used for testing Cardiac Marker panels and D dimer. (See D5445) |
| **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 |

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| | 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 observations, review of quality control records, the laboratory's own IQCP, patient test records and interview of facility personnel found the laboratory failed to test at least two levels of quality control materials on the two Alere triage meters, at the frequency defined in their own individualized quality control plan (IQCP) approved November 1, 2017. The findings included: 1. Observations made during the tour of the facility found that the laboratory had two Alere triage meters available for use. The serial numbers for the two meters were: SN 0007751 SN 00074364 The laboratory used the moderately complex Cardiac Marker Panel and the Ddimer cartridges for testing patient specimens. 2. Review of the laboratory's own IQCP for D dimer (effective July 1, 2016) found in the quality control plan: "External liquid QC ( 1 known normal and abnormal) would be performed per lot/shipment and before or concurrently with placing these reagents in use for patient testing. External liquid QC ( 1 known normal and abnormal) performed with each instrument replacement, part replacement and preventive maintenance. External liquid QC ( 1 known normal and abnormal) performed with each software update. External liquid QC ( 1 known normal and abnormal) performed at least every 30 days." 3. Review of quality control records between November 2017 and May 2018 found that the laboratory failed to test two levels of quality control testing on each of the Alere Triage meters as follows: Instrument SN 0007751 November 2017 - No documented quality control procedures for Ddimer. December 2017 - No documented quality control procedures for Ddimer. January 2018 - level 2 quality control tested on January 31, 2018 February 2018 - No documented quality control procedures for Ddimer or Cardiac Markers. March 2018 - level 2 quality control tested for D dimer on March 5, 2018 level 1 quality control tested for Cardiac Markers on March 5, 2018 and March 6, 2018 April 2018 - No documented quality control procedures for Ddimer. May 2018 - No documented quality control procedures for Ddimer. Instrument SN000074364 November 2017 - No documented quality control procedures for Ddimer. December 2017 - No documented quality control procedures for Ddimer. January 2018 - Level 1 quality control tested on January 31, 2018 February 2018 - No documented quality control procedures for Ddimer March 2018 - level 1 quality control tested for D dimer on March 5, 2018 4. Review of patient test records found: The laboratory tested 16 patient specimens for Cardiac Markers between March 13, 2018 and March 25, 2018 without testing two levels of quality control materials every 30 days when using Instrument SN 0007434364. The laboratory tested 25 patients for Ddimer between November 1, 2017 and April 5, 2018 without testing two levels of quality control materials every 30 days when using Instrument SN 0007434364. The laboratory tested 7 patient specimens for Cardiac Markers without testing two levels of quality control materials every 30 days when using Instrument SN 0007751. Four were tested between February 28, 2018 and April 5, 2018 and 3 additional patients tested between May 6, 2018 and May 16, 2018. The laboratory tested 25 patients for Ddimer between November 1, 2017 and June 15, 2018 without testing two levels of quality control materials every 30 days when using Instrument SN 0007434364. 5. Interview of the Laboratory Director conducted on June 13, 2018 at 2:21 PM confirmed that the laboratory did not test two levels of quality control material on each analyzer at least once every thirty days as defined in their own IQCP. She stated that she thought because they were using a common cartridge, QC procedures were only required on each cartridge, not each analyzer. |
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| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Observations, review of policies and procedures, quality control records, patient test records and interview of facility personnel found the laboratory director failed to provide overall management and direction. The laboratory director failed to ensure that the quality control program was established and maintained for D dimmer and Cardiac Markers tested on the Alere Triage meter. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on observations, review of quality control records, the laboratory's own IQCP, patient test records and interview of facility personnel found the laboratory director failed to and maintain the quality control program for D dimmer and Cardiac Marker Panels. The laboratory failed to test at least two levels of quality control materials on the two Alere triage meters, at the frequency defined in their own individualized quality control plan (IQCP) approved November 1, 2017. (see D 5445) |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on observations, review of quality control records, patient test records and interview of facility personnel found that the technical consultant failed to establish and maintain the quality control program for analytes tested on the Alere triage meters. The laboratory failed to test at least two levels of quality control material at least once each month, and with each new lot and shipment of the Alere Cardiac Marker panel and the D Dimer tested on the two Alere Triage meters (SN 0007751 and SN 00074364). (see D5445) |