| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0660553 | 03/14/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Starr County Memorial Hospital | 128 N Fm 3167, Rio Grande City, 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. |
| **D3033** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)(i)<br><br>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's method comparison studies from 2017 and 2018, and staff interview, it was revealed the laboratory failed to retain the records for January 2018. The findings were: 1. A review of the laboratory's method comparison studies from 2017 and 2018 revealed the laboratory failed to retain the records for the comparison done in January 2018 for Blood Gas testing performed on the ABL800 and ABL80 analyzers and Hemoglobin testing on the ABL800, ABL80, and Sysmex XS-1000i hematology analyzer. 2. The laboratory was asked to provide the missing |

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| | documentation. No documentation was provided. 3. An interview with the technical consultant on 03/14/2019 at 1240 hours in the conference room - after her review of the records - confirmed the findings. |
| **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 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 review of the laboratory's verification records, and staff interview, it was revealed the laboratory failed to have documentation of complete studies. The findings were: 1. A review of the laboratory's verification studies performed on the Vidas 3 (serial number VN04841) for D dimer testing revealed the laboratory failed to have documentation of verifying precision. 2. A review of the laboratory's verification studies performed on the Illumigene (serial number IP2869) for C. difficile testing revealed the laboratory failed to have documentation of verifying precision. 3. A review of the laboratory's verification studies performed on the Illumigene (serial number IP2869) for Group B streptococcus testing revealed the laboratory failed to have documentation of verifying precision. 4. A review of the laboratory's verification studies performed on the Illumigene (serial number IP2869) for Group A streptococcus testing revealed the laboratory failed to have documentation of verifying precision. 5. The laboratory was asked to provide documentation of performing the required studies. No documentation was provided. 6. An interview with the technical consultant on 03/13/2019 at 1438 hours in the conference room - after her review of the records- confirmed the findings. |
| **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 review of the laboratory's instrumentation, review of the laboratory's Individualized Quality Control Plans, and staff interview, revealed the laboratory failed to have documentation of establishing new Individualized Quality Control Plans with a change in instrumentation. The findings were: 1. A review of the laboratory's instrumentation revealed the laboratory the laboratory received Illumigene analyzer |

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| | (serial number IP2869) for the analysis of C difficile, Group A streptococcus, and Group B streptococcus in April 2018. 2. A review of the laboratory's Individualized Quality Control Plans revealed the laboratory established a plan for the previous analyzer (serial number IP2783). There was not documentation of a IQCP being performed on the new analyzer. 3. The laboratory was asked to provide documentation of performing an IQCP on the new analyzer. No documentation was provided. 4. An interview with the technical consultant on 03/13/2019 at 1438 hours in the conference room - after her review of the records- confirmed the findings. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation and staff interview it was revealed the laboratory failed to ensure the nursing staff who assisted in the monitoring of the blood bank alarm system understood what the alarm was for and what steps to follow when it was sounding. The findings were: 1. Surveyor observation of alarm checks performed by the laboratory on 03/14/2019 at 1315 hours revealed the blood bank refrigerator alarm sounded in the laboratory and the nurses station on the first floor of the hospital. The alarm was sound while there were 3 - 4 nurses at various times at the station. After 5 minutes of the alarm going off, laboratory personnel switched off the alarm. The surveyor asked 4 nurses present what the alarm meant. They each stated they weren't sure but assumed it had something to do with the laboratory. 2. The laboratory was asked to provide documentation of a procedure or of training of the nursing personnel to ensure they knew what the alarm indicated and the steps to take when it was sounding. No documentation was provided. 3. An interview with the technical consultant on 03/14/2019 at 1320 hours in the laboratory confirmed the findings. |
| **D5559** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(e)(f)<br><br>(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the facility's transfusion reaction policies and staff interview, it |

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| | was revealed the laboratory failed to have documentation of defining criteria used to assist in identifying potential transfusion reactions. The finding were: 1. A review of the laboratory's policies revealed the laboratory identified the terms of "fever", "hypertensive" and "hypotensive" and possible indicators of a transfusion reaction. 2. The laboratory was asked to provide documentation of the criteria to be used to define each of the identified terms. No documentation was provided. 3. An interview with the technical consultant on 1330 hours in the conference room - after her review of the records- confirmed the findings. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's maintenance records from 2017 on the Sysmex CA1500 analyzer and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when pressure was documented outside the manufacturer's acceptability range. The findings were: 1. A review of the laboratory's maintenance records from 2017 on the Sysmex CA1500 analyzer revealed the acceptable range for instrument pressure was identified as 1.0 - 1.1 kg/cm. 2. Further review of the maintenance records identified the following days when the documented pressure was outside the acceptable range: Date Pressure 3/18 1.110 3/19 1.118 3/21 1.171 3/29 1.189 9/26 1.144 9/28 1.118 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. An interview with the technical consultant on 03/14 /2019 at 1020 hours in the conference room - after her review of the records - confirmed the findings. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's test menu, review of the laboratory's annual |

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| | calculation verifications form 2017 and 2018, and staff interview, it was revealed the laboratory failed to have documentation of verifying calculations for MCV, MCH, MCHC, and MPV. The findings were: 1. A review of the laboratory's test menu revealed the laboratory reported out the following calculated tests results: MCV MCH MCHC MPV 2. A review of the laboratory's annual calculation verifications from 2017 and 2018 revealed the laboratory failed to have documentation of verifying these calculations. 3. The laboratory was asked to provide documentation of verifying the calculations in 2017 and 2018. No documentation was provided. 4. An interview with the technical consultant on 03/14/2019 at 1400 hours in the conference room - after her review of the records- confirmed the findings. Key MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration MPV - mean platelet volume |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's verification studies, and staff interview, it was revealed the laboratory director failed to ensure studies were complete prior to documenting his approval of the studies. The findings were: 1. A review of the laboratory verification studies performed on the Dimension ExL (serial number DE271283) for the test of LDL cholesterol revealed the laboratory director documented his approval of the studies on 8/7/2017. Review of the records revealed the accuracy of the system was not completed until 8/11/2017. 2. A review of the laboratory's verification studies performed on the Dimension ExL (serial number DE271283) for the test Vitamin D revealed the laboratory director documented his approval of the studies on 12/29/2017. Review of the records revealed the following studies were not performed: - accuracy - verification of patient normal ranges 3. An interview with the technical consultant on 03/13/2019 at 1445 hours in the conference room - after her review of the records - confirmed the findings. |