| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 17D0450748 | 10/11/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Morris County Hospital | 600 North Washington, Council Grove, KS | |

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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| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate the results obtained on proficiency testing for analytes that were assigned a proficiency testing score that did not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part). Findings Include:<br>a. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation found the laboratory received a score of "Not Graded" on the following proficiency testing samples: 2 2nd Testing Event 2 Hematology Sample: BCI-14 Analyte: Blood Cell ID Reported Result: Blast Expected Result: Blasr Sample: BCI-10 Analyte: Blood Cell ID Reported Result: Neutrophil segmented Expected Result: See commentary b The surveyor requested documentation of self-assessment or self-evaluation for the samples that were not graded by the PT provider from the Technical Consultant (TC). The TC stated the laboratory did not have documentation of self-assessment or self-evaluation for the not graded samples. The interview occurred 10/11/2018/2018 at 09:30 hrs. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>A review of Temperature logs and interview with staff revealed the laboratory failed to establish a temperature log for laboratory drawing room to monitor temperature for vacationer tubes. Findings were as follows: a. Based upon review of manufacture's requirements the laboratory failed to establish a temperature log and range for the vacationer tubes 4-25 degrees C . b. At the time of the survey 10/11/2018 the laboratory failed to produce corrective action documentation of temperature, This was confirmed by the Technical Consultant from the CMS 209 form on 10/11/2018 at 1000 hours. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with Technical Consultavt from the CMS 209 10 /11//2018 at 09::30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>A review of Quality Assessment and Interview with staff revealed the laboratory failed to have a plan that covered all aspects of the laboratory. Finding were as follows: 1. Based upon the Quality Assessment Action plan the laboratory failed to |

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| | establish a action plan for any manual calculation ( INR) for any analyte that is reported . Therefore, the accuracy or reliability of the analyte cannot be verified. This was confirmed in interview with Technical Consultant on 10/11/2018 at 10;30 hrs. |