| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number | (X3) Date Survey Completed |
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| | 17D0451259 | 11/28/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ascension Via Christi Emergency Dept In Wellington | 1323 North A Street, Wellington, 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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| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Review of Ortho MTS ID-Tipmaster pipetor A63006231 blood bank function check, manufacturer's instructions, and staff interview revealed that the laboratory failed to assure that the pipetor used for Immunohematology testing with the Ortho MTS Gel system was operating within the manufacturer's specification. Findings were: 1. Review of January 2, 2018 Ortho MTS ID-Tipmaster pipetor A63006231 verification record from Streck of the 12.5 microliter (ul) setting showed the percent recovery was 106.94%, which Streck recommends an acceptable limit of 100% +/- 3%. In addition, the Streck record documented a correlation verification (c. v.) of 11.44% with a mean (average) volume of 13.4 ul. For this pipette, no corrective action or documentation was available for 2018 at the time of the survey for the elevated percent recovery or elevated c. v. 2. Review of the Ortho MTS ID-Tipmaster pipetor manufacturer's instruction revealed the acceptable c. v. for the 12.5 ul setting was 10%. 3. Technical Consultant #1 (refer to laboratory testing personnel form CMS-209) confirmed the Ortho MTS ID-Tipmaster pipetor A63006231 was used to dispense red blood cells for patient testing from January 2018 to November 2018 into the Ortho MTS Gel Cards. 4. The above information was confirmed during interview by the Technical Consultant #1 at 9:02 a.m. on November 28, 2018. Review of the manufacturer's package instructions, laboratory's procedure, laboratory patient testing logs, and staff interview revealed that the laboratory failed to assure the manufacturer's instructions were followed when performing patient testing. Findings were: 1. BD Package insert |

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| | stated, "allow the antigen to warm to room temperature (23 to 29 degrees Celsius) before use." "Refrigerated antigen may result in decreased sensitivity of the test." 2. Review of the Macro-Vue RPR Card Test Becton Dickinson Laboratory Procedure stated "Bring serum and antigen up to 23 to 29 degrees Celsius at time of testing." 3. Review of patient testing logs reveals temperatures below the acceptable range of 23 degrees Celsius 15 of 21 days of testing during 2018. 4. The above information was confirmed during interview by the Technical Consultant #1 (refer to laboratory testing personnel form CMS-209) at 12:22 p.m. on November 28, 2018. |
| **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>Based upon the lack of procedures and interview with the Technical Consultant #1 (refer to Laboratory Personnel Report (CMS-209)) at 08:34 am on November 28, 2018 revealed that the lab did not have a written quality assurance (QA) procedure regarding pipette maintenance and calibrations available for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the analytic systems specified in 493.1251 through 493.1283. No quality assessment (QA) policies or procedures are available and no QA activities are documented. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based upon a review of the laboratory's personnel competency assessment policy and records and staff interview, the laboratory's technical consultant (TC) failed to perform the competency assessment of all trained testing personnel. Findings were: 1. Review of blood gas competency assessment of testing person (TP) number (#) 10 (see laboratory personnel report form CMS-209) was performed by testing personnel #8 instead of the technical consultant on 12-19-2017. 2. Review of hematology, coagulation, and bacteriology competency assessments from the period July 2017 to December 2018 revealed that testing person # 3, as identified on Form CMS-209 was performing competency assessments instead of the technical consultant/supervisor for the following testing personnel listed on form CMS-209. Bacteriology competency assessments TC #1 - performed from 9/10/2018 to 9/17/2018 Hematology competency assessments TC #1 - performed from 9/25/2017 to 10/11/2017, and 9/26 /2018 TC #2 - performed 8/24/2017, 10/28/2017, and 10/30/2018 General Supervisor (GS) #1 - performed 7/10/2017, 7/26/2017, 10/11/2017, 10/17/2017, and 10/18/2018 TP #4 - performed 1/4/2018 to 1/12/2018, 8/1/2018, and 8/10/2018. Coagulation competency assessments TC #1 - performed 7/20/2017 and 10/10/2018 TC #2 - performed 9/20/2018 GS #1 - performed 7/20/2017 and 10/5/2018 TP #4 - performed |

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| | 1/4/2018 to 1/10/2018 and 8/8/2018 to 8/15/2018 3. The above findings were confirmed during interview with the TC #1 at 9:02 am on November 27, 2018. |