Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453125	06/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Centura St Catherine Hospital - Dodge City	3001 Avenue A, Dodge City, 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
D0000	A complaint survey was conducted June 12, 2024 to June 19, 2024. It was determined that Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F. R. 493.801 Condition: Enrollment and Testing Of Samples 42 C.F.R. 493.1250 Condition: Analytic Systems
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the procedure manual, immunohematology quality control (QC), patient test records, specialty information, 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records, and interview with the director of laboratory quality, the laboratory failed to enroll in PT for antibody identification for weak (passive) D antibody. Findings: 1. Review of the immunohematology procedure manual showed a procedure "Antibody Identification" currently unapproved by the laboratory director as of 6/12/24. 2. 20 patients were tested for weak D antibody identification from 8/23/23 to 5/14/24. 3. The weak D antibody identification was not designated under immunohematology, performed at this lab, on the Form CMS-116. 4. Review of API PT immunohematology records for 2023 Event 3 and 2024 Event 1

	showed no enrollment records for antibody identification, only antibody screening. 5. Interview with the director of laboratory quality on 6/13/24 at 11:45 AM confirmed the laboratory failed to enroll in proficiency testing for antibody identification.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on the lack of documentation, lack of Individual Quality Control Plan (IQCP), lack of quality control values on patient testing dates and interview with technical consultant #3, failed to perform QC every day of testing for the test AmniSure Rupture of Membrane (ROM) (refer to D5445); the laboratory failed to perform QC every 8 hours for arterial blood gases (refer to D5537) and every day of patient testing for the Epoc analyzers (refer D5447); failed to follow manufacturer's instructions on the Resolve Panel A used for antibody identification (AB ID) testing (refer to D5479); failed to perform QC every day of patient testing, with no established IQCP on two of two i-STATs test (refer to D5545); failed to periodically test the high alarm on the ultra cold freezer, Thermo Scientific TSU, since installed in April 2007 (refer to D5555).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the procedure for normal values for the Sysmex XN 450 and XN 550 hematology analyzers, patient test reports, patient test volumes, and

	interview, the laboratory failed to include normal values for six of twenty-two analytes in hematology determined by the laboratory. Findings: 1. Review of the laboratory policy "Value Sheet (CBC/Reticulocyte/Body Fluid Reference Intervals and Critical Values)" for the Sysmex XN 450 and XN 550 hematology analyzers revealed the laboratory failed to have normal range established for six of twenty-two analytes for the complete blood count (CBC) with auto differential (Auto Diff) reported by these analyzers. Neutrophils % Percent reference range not established Immature Granulocytes % (Auto) Percent reference range not established Lymphocytes % Percent reference range not established Monocytes % Percent reference range not established Eosinophils % Percent reference range not established Basophils % Percent reference range not established 3. The laboratory revealed approximately 13,000 patient reports were reported without verified normal ranges. 4. Interview with the technical consultant #2 and Quality Specialist for Hematology on 6 /13/24 at 3:00 p.m. confirmed, the laboratory failed to include normal values in the procedure manual for six of the twenty-two analytes reported by the laboratory.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on an absence of thermometer function check records, certificates of accuracy, protocols for thermometer function checks, lack of maintenance checks for the biosafety cabinets (BSC) and interview with technical consultant (TC) #2, the laboratory failed to perform a function check protocol for twelve of fifteen thermometers and two of two BSCs. Findings: 1. No documentation was available for current function checks on twelve of fifteen thermometers that expired 11/2023 and 12 /2023 at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on twelve of fifteen thermometers that expired 11/2023 and 12/2023 at the time of survey. 3. Protocols for the function checks of thermometers were not made available at the time of survey. 4. No documentation of maintenance checks were available for two of two BSCs at the time of survey. 5. Protocols for the maintenance checks for the BSCs were not made available at the time of survey. 6. Interview with TC #2 on 6/13/24 at 1:00 p.m. confirmed, the laboratory failed to perform a function check protocol for twelve of fifteen thermometers and two of two BSCs.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation for AmniSure Rupture of Membrane (ROM) test, lack of an individualized quality control plan (IQCP), patient test results and interview with technical consultant (TC) #3, the laboratory failed to perform QC at least once each day of patient testing for Amnisure ROM patient testing. Findings: 1. Review of the ROM QC documents for AmniSure test system revealed the laboratory failed to perform external QC each day of testing from 3/5/23 to 6/13/24. 2. No approved IQCP for the AmniSure ROM test system was provided at the time of survey.. 3. Interview with the TC#3 on 6/12/24 at 11:15 a.m and 3:15 p.m respectively confirmed the laboratory failed to perform QC at least once each day of patient testing for the AmniSure ROM patient testing. 4. The laboratory reported 82 ROM patient tests.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation for six of six Siemens Epocs, FDA test complexity categorization, procedure manual records and patient test results from 4/1/23 to the date of survey, and interview, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations for 1334 patient results reported. Findings: 1. Review of quality control (QC) documentation for six of six Siemens Epocs, patient test results, and interview with the technical consultant (TC) #3, the laboratory failed to perform QC of at least two control materials of different concentrations each day of patient testing. 2. The Siemens Epoc cartridge includes the following tests: total carbon dioxide (TCO2). Sodium (Na+), Potassium (K+), Ionized Calcium (Ca++), Chloride (Cl-), Hematocrit (HCT), Glucose (Glu), Lactate (Lac), BUN and Creatinine (Crea) which are categorized as moderate complexity tests and require quality control at least once each day of patient testing with two control materials of different concentrations. 3. . Review of the Epocs QC documents for the six Siemens Epoc test system revealed the laboratory failed to perform external QC to include two control materials of different concentrations each day of patient testing for 1334 patients. 4. The six Siemens Epocs affected are: # 45121, # 31100, # 45173, # 45238, # 45248 and # 46218. 5. Interview with the TC#3 on 6/12/24 at 3:10 p.m. confirmed the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations for 1334 patient results reported from 4/1/23 to 6/12/24.
D5479	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the immunohematology lab, review of antibody ID worksheets, Form CMS-116 application provided at survey, lack of patient cell results, lack of quality control documents, and manufacturer's instructions, the laboratory failed to follow the manufacturer's specifications for using reagents for the Ortho Diagnostics 0.8% RESOLVE Panel A. Findings: 1. Observation of the immunohematology lab showed a plastic bin labeled Antibody ID. The Form CMS-116 completed application provided at survey did not list antibody identification as a subspecialty performed. 2. Review of immunohematology documentation showed 20 patient test results recorded on the Ortho Clinical Diagnostics Panel A Antigram Antigen Profile worksheets from 8/30/23 to 5/6/24. a. No documentation of the patient's cells tested with the patient's serum as an autologous control was present on 20 of 20 test worksheets. b. No documentation of any quality control process on the RESOLVE Panel A reagents for the 20 patient results was provided at the time of survey. 3. Review of the instruction for use for the Otho 0.8% Panel A revealed under "Control of Error" the following: a. A control consisting of the serum and autologous red blood cells prepared according to the ID-Micro Typing System Instructions for Use should be testing in parallel with 0.8% RESOLVE Panel A. A positive reaction indicates patient abnormality which must be resolved before the test results can be interpreted. b. Quality Control requirements will vary based on regional and national guidance's, standards, regulations, and professional preferences. Each laboratory must develop specific quality control procedures accordingly. 4. Phone interview with the general supervisor #2 on 6/17/24 at 12:17 p.m. confirmed the labortory failed to follow the manufacturer's specifications for using reagents for the Ortho Diagnostics 0.8% RESOLVE Panel A.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation for six of six Siemens Epocs, patient test results, and interview with the technical consultant (TC) #3, the laboratory failed to perform QC at least once every eight hours of patient testing for Arterial Blood Gas (ABG) patient testing. Findings: 1. The Siemens Epoc ABG includes the following tests: pH, partial pressure of carbon dioxide (pCO2) and partial pressure of oxygen (pO2). 2. Review of the ABG QC documents for the six Siemens Epoc test system revealed the laboratory failed to perform external QC every eight hours for 1334 patients. 3. The six Siemens Epocs affected are: # 45121, # 31100, # 45173, # 45238, # 45248 and # 46218. 4. Interview with the TC#3 on 6/12/24 at 3:10 p.m.

	confirmed the laboratory failed to perform QC at least once eight hours of patient testing for the six Siemens Epocs for ABG patient testing.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation for two of two Abbott i-STATs, lack of an individualized quality control plan (IQCP), patient test results, and interview with technical consultant (TC) #3, the laboratory failed to perform QC every eight hours of patient testing for two of two Abbott i-STAT analyzers for Activated Clotting Time (ACT). Findings: 1. Review of the ACT QC documents for the two Abbott i-STAT test system revealed the laboratory failed to perform external QC from 6/2/23 to 6/13/24. 2. No approved IQCP for the Abbott i-STAT test system was provided at the time of survey. 3. The two Abbott i-STATs affected are: #376914 (Cath Lab) and #30504 (Main Lab). 4. Interview with the TC#3 on 6/12/24 at 11:15 a. m. and 3:15 p.m. respectively confirmed the laboratory failed to perform QC every eight hours each day of patient testing for the Abbott i-STAT for ACT testing. 5. The laboratory reported 82 ACT patient tests.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (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. This STANDARD is not met as evidenced by: Based on the lack of high alarm check records for the Thermo Scientific TSU ultra freezer, review of fresh frozen plasma (FFP) and cryoprecipitate records, and interview with the laboratory manager, the laboratory failed to store FFP and cryoprecipitate blood products in a freezer that had an adequate temperature alarm system that was regularly inspected. Findings: 1. The laboratory stores FFP and cryoprecipitate in an ultra cold freezer from Thermo Scientific. At the time of survey, no documentation of high alarm checks were provided for 2022, 2023, and to date of survey 2024. The laboratory manager stated that "the freezer had not been tested for high alarms since its installation in April of 2017." 2. Request for blood product issue records revealed 19 units of FFP and no units of cryoprecipitate were issued from April 2017 to date of survey. 3. Interview with the laboratory manager on 6/13/24 at 10:10 a.m. confirmed, the laboratory failed to store FFP and cryoprecipitate blood products in a freezer that had an adequate temperature alarm system that was regularly inspected.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to provide overall management and direction in accordance with 493.1445. (refer to D6106).
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the review of the procedures in immunohematology for the "Blood Product Support: Emergency Release of Blood Products," "Testing: Rh Immune Globulin (RhIG) Candidate Evaluation," "Testing: Transfusion Reaction Workup," "Testing: Antibody Identification" and interview, the Laboratory Director failed to ensure the above procedures were approved prior to patient testing. Findings: 1. The date the current individual became the official Laboratory Director was 4/1/2023. 2. Review of the procedure "Blood Product Support: Emergency Release of Blood Products" showed no approval by the Laboratory Director as of 6/13/2024. 3. Review of the procedure "Testing: Rh Immune Globulin (RhIG) Candidate Evaluation" showed no approval by the Laboratory Director as of 6/13/2024. 4. Review of the procedure "Testing: Transfusion Reaction Workup" showed no approval by the Laboratory Director as of 6/13/2024. 5. Review of the procedure "Testing: Antibody Identification" showed no approval by the Laboratory Director as of 6/13/2024. 6. Interview with the CommonSpirit Quality Specialist on 6/13/24 at 12:35 p.m. confirmed, the laboratory director failed to review and approve the procedures for the "Blood Product Support: Emergency Release of Blood Products," "Testing: Rh Immune Globulin (RhIG) Candidate Evaluation," "Testing: Transfusion Reaction Workup" and "Testing: Anitbody Identification" prior to patient testing.