

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 17D0648262	<b>(X3) Date Survey Completed</b> 03/01/2019
<b>Name of Provider or Supplier</b> Hospital District #1 Of Crawford County	<b>Street Address, City, State</b> 302 N Hospital Drive, Girard, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing and interview with technical supervisor #2 on March 1, 2019 at 2:00 PM confirmed the laboratory failed to prove accuracy two times a year for the analyte ammonia in 2018.</p>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assessment and interview with the technical supervisor on March 1, 2019 at 1:00 PM confirmed the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. Refer to D5441, D5481</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p>

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 review of quality control records, temperatures, procedure manual and interview, the laboratory failed to meet the condition: Analytic systems. The laboratory failed to ensure blood bank procedure was appropriate (refer to D5401), failed to ensure proper storage (refer to 5413), failed to monitor controls (refer to 5441), failed to have complete Individualized quality control program (refer to 5445), failed to perform controls each day of patient testing (refer to D5449), failed to check each batch of media for its ability to support growth (D5447), failed to ensure quality control is acceptable (refer to D5481) and failed ensure blood gas quality control is performed every 8 hours (refer to D5537).

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on review of blood bank procedures and interview with the technical supervisor #2 on March 1, 2019 at 1:00 PM confirmed the laboratory failed to have a step by step procedure for looking at previous antibody patient cards and in the patient antibody book for known antibodies before starting a crossmatch.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:  
Based on review of freezer temperature logs and interview with technical supervisor #2 the laboratory failed to follow storage requirements for Bio-Rad controls for four of twenty eight days. Findings: 1. Package insert for Bio-Rad controls states "store -20 to -70 degrees Celsius". Review of freezer temperature log for February showed

temperature above -20 on February 13, 17, 18 and 27. 2. Interview with the technical supervisor #2 on March 1, 2019 at 1:00 PM confirmed the laboratory failed to follow storage requirements for Bio-Rad controls.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of Sysmex XS1000i quality control (QC), Protime QC, insight reports and interview with the technical supervisor the laboratory failed to monitor the daily Sysmex QC, protime QC and detect immediate errors and monitor over time the accuracy and precision of test performance. Findings: 1. Review of Sysmex daily QC showed no acceptable ranges, QC from January 2019 to date March 1, 2019 did not have acceptable QC ranges to detect errors. 2. Review of protime daily QC showed normal controls were shifting high between 1 and 2 standard deviations for December 2018 and high controls for protimes were shifting up in January 2019 with controls out on 1/20/19. 3 Interview with the technical supervisor #2 on March 1, 2019 at 1:00 PM confirmed the laboratory failed to monitor the daily Sysmex QC, protime QC and detect immediate errors and monitor over time the accuracy and precision of test performance.

**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 microscan individualized quality control plan (IQCP) and interview with technical supervisor #2 on March 1, 2019 at 1:00 PM confirmed the laboratory failed to include a quality control plan with their IQCP.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

	<p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Bactec media blood culture bottle and interview with the technical supervisor #2 on March 1, 2019 at 2:00 PM confirmed the laboratory failed to check each batch of media for its ability to support growth.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of serum pregnancy quality control (QC), clostridium difficile QC and interview with the technical supervisor #2 on March 1, 2019 at 2:00 PM confirmed the laboratory failed to include a negative and positive control material each day of patient testing.</p>
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review d-dimer quality control (QC) and interview with the technical supervisor #2 the laboratory failed to ensure d-dimer QC acceptability before reporting patient test results. Findings: 1. Review of d-dimer QC for February showed low control for February 17 and 18 was not within acceptable limits and three patient test results were reported. 2. Interview with the technical supervisor on March 1, 2019 at 2:00 PM confirmed the laboratory failed to ensure d-dimer QC acceptability before reporting patient test results.</p>
<b>D5537</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.1267(b)(d)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of blood gas quality control (QC) and interview with technical supervisor #2 on March 1, 2019 at 1:00 PM confirmed the laboratory failed to 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 in 2017, 2018 and to date 2019.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of quality control program, quality assurance and interview the director failed to provide overall management and direction; failed to maintain the quality control program (refer to D6093); failed to ensure quality assessment programs are adequate (refer to D6094) and failed to ensure patient test results are reported only when the system is functioning (refer to D6097).</p>
<p><b>D6093</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review d-dimer quality control (QC) refer to D5481, Sysmex QC, protime QC refer to D5441, serum pregnancy QC refer to D5449, blood gas QC refer to D5537 and interview with the technical supervisor on March 1, 2019 at 1:00 PM confirmed the laboratory director failed to ensure quality control was performed and acceptable.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of Sysmex QC, protime QC refer to D5441, d-dimer QC refer to D5481 and interview with the technical supervisor on March 1, 2019 at 1:00 PM confirmed the laboratory director failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

**D6097**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(7)

The laboratory director must ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Based on review of d-dimer quality control (QC) refer to D5481, Sysmex QC, protime QC refer to D5441 and interview with the technical supervisor on March 1, 2019 at 1:00 PM confirmed the laboratory director failed to ensure that patient test results are reported only when the system is functioning properly.