Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1013631	07/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jordan Valley Community Health Center	440 E Tampa, Springfield, MO	

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
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 observation of refrigerator reagents, refrigerator temperature logs and interview with the general supervisor (GS), the laboratory failed to follow manufacturer's instructions for storing Vitros 5600 calibrators for 14 of 132 days. Findings: 1. Observation of the laboratory refrigerator showed six boxes of chloride calibrators lot # 4010-0739-8746 expiration date 11/1/22 storage requirements 2 to 8 degrees Celsius, six boxes of albumin calibrators lot # 0932-3377-8388 expiration date 10/1/22 storage requirements 2 to 8 degrees Celsius and six boxes of calcium calibrators lot # 0349-0606-7120 expiration date 9/1/22 storage requirements 2 to 8 degrees Celsius. 2. Review of 2021 refrigerator temperature logs showed on 5/14, 5 /20, 5/25, 5/27, 5/28, 6/4, 6/7, 6/10, 6/21, 7/1, 7/2, 7/8, 7/9, 7/12 the refrigerator temperature was not within 2 to 8 degrees Celsius. 3. Interview with the GS on July 20, 2021 at 10:30 AM confirmed the laboratory failed to follow manufacturer's storage requirements for Vitros 5600 calibrators.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of performance verification procedures for the Ortho Diagnostics workstation, ABO, Rh, antibody screen and interview with the general supervisor (GS) the laboratory failed to verify accuracy and precision before reporting patient test results. Findings: 1. Review of performance verification procedures for the Ortho Diagnostics workstation, ABO, Rh and antibody screen showed the laboratory failed to verify accuracy and precision. 2. Interview with the GS on July 20, 2021 at 10:30 AM confirmed the laboratory failed to ensure performance verification procedures were adequate before reporting patient test results.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of "Sysmex XN-550 CLSI" procedure, 2019/2020 calibration records for the Sysmex XN-550 hematology analyzer and interview with the general supervisor (GS), the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of the hematology analyzer in 2019/2020. Findings: 1. Review of the"Sysmex XN-550 CLSI" procedure states "The laboratory must verify calibration every six months or on an "as-needed" basis to ensure accuracy of system." 2. Review of 2019, 2020 and 2021 calibration records for the Sysmex XN-550 hematology analyzer showed the laboratory failed to perform a calibration for the Sysmex XN-550 following manufacturer's recommended frequency of every six months in 2019/2020 for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 3. Interview with the GS on July 20, 2021 at 10:00 AM confirmed the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of the Sysmex XN-550 hematology analyzer in 2019/2020.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or

	instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of Medtox Scan analyzers and interview with the general supervisor (GS), the laboratory failed to evaluate and define a relationship between test results using the same type of instrument twice a year for 2019, 2020 and to date July 20, 2021. Findings: 1. Review of Medtox Scan drug testing analyzers #1 and #2 for analytes: cannabinoids, phencyclidine, cocaine, methamphetamine, opiates, amphetamine, benzodiazepines, tricyclic antidepressants, methadone, barbiturates, oxycodone, propoxyphene, and buprenorphine showed no documentation of evaluation between test results using the same type of instrument twice a year for 2019, 2020 and to date July 20, 2021. 2. Interview with the GS on July 20, 2021 at 10: 00 AM confirmed the laboratory failed to evaluate and define a relationship between test results using the same type of instrument twice a year for 2019, 2020 and to date July 20, 2021.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the 2019/2020/2021 proficiency testing (PT) records and interview with the general supervisor (GS), the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the hematology/coagulation PT records for the first PT testing event of 2020 showed the laboratory obtained not graded results for blood cell identification, samples ECI-01 - 05. The laboratory could not provide documentation to show appropriate staff evaluated the not graded results to identify any problems that may require corrective action. 2. Review of the hematology/coagulation PT records for the first PT testing event of 2021 showed the laboratory obtained not graded results for blood cell identification, samples ECI-01 - 05. The laboratory could not provide documentation to show appropriate staff evaluated the not graded results to identify any problems that may require corrective action. 3. Interview with the GS on July 20, 2021 at 10:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.