Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0701558	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Warm Valley Healthcare	29 Black Coal Drive, Fort Washakie, WY	

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
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 new instrument and new test method verification study review, lack of documentation, and staff interview, the laboratory failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing for 1 of 4 new test verification studies reviewed (Alere D-dimer). Since implementation the laboratory had performed 136 patient tests. The findings were: 1. Review of the 6/2020 new instrument verification study for the Alere D-dimer analyte failed to show the performance specification of precision and reportable range had been verified by the laboratory prior to testing patient samples. In addition, the laboratory failed to confirm the manufacturer's normal values were appropriate for the laboratory's patient population. The verification study was signed by the laboratory director on 9/20/21. 2. Interview with the laboratory manager and the lead technologist on 4/28/22 at 12:58 PM confirmed the verification studies were incomplete.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for sodium, potassium, and chloride analyzed on the Dimension EXL 200 chemistry analyzer for 2 of 2 years reviewed (2020, 2021). The findings were: 1. Review of the laboratory's records showed a calibration verification had been performed on 2/28/20 and 1/21/21. 2. Interview with the laboratory consultant on 4/28/22 at 12:30 PM confirmed the calibration verification had not been performed every 6 months as required.
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 quality control (QC) record review, review of the patient testing logs, lack of documentation, and staff interview, the laboratory failed to perform two levels of quality control each day of testing for the Alere D-dimer analyte for 13 of 15 months reviewed (January through April 2021, June 2021 through October 2021, December 2021 through January 2022, March 2022) and the Medtox urine toxicology screen for 4 of 5 months reviewed (December 2021 through March 2022). This failure affected patient testing on 75 D-dimer tests and 15 urine toxicology screens. The findings were: 1. Review of the QC records and patient testing logs for the Alere D-dimer tests showed the following concerns: a. Sixteen D-dimer tests were performed in January 2021 with no QC recorded. b. Review of the February, March, and April 2021 log sheets showed QC was performed on the first of the month which did not correspond

	to the dates of the 21 patient samples tested. c. Review of the May, June, July, August, September, and October 2021 log sheets showed QC was performed at the first of the month which did not correspond to the dates of the 30 patient samples tested. d. Review of the December 2021 log sheets showed QC was performed on 12/1 /21 and 2 patient samples were tested on 12/2/21. e. Review of the January 2022 log sheets showed QC was performed on 1/18/22. Two patient samples were tested on 1 /25/22 and 1 patient sample was tested on 1/29/22. f. Review of the March 2022 log sheets showed QC was performed at the first of the month which did not correspond to the dates of the 3 patient samples tested. 2. Review of the QC records and patient testing logs for the Medtox urine toxicology screen showed the following concerns: a. Review of the December 2021 log sheets showed patient tests were performed on 12 /7, 12/13, 12/14, 12/16, 12/23, and 12/28. There was no evidence QC had been performed. b. Review of the January 2022 log sheets showed patient tests were performed on 1/3 and 1/24. There was no evidence QC had been performed. c. Review of the February 2022 log sheets showed patient tests were performed on 2/18 and 2/24. There was no evidence QC had been performed. d. Review of the March 2022 log sheets showed patient tests were performed on 3/8, 3/16, 2 patients on 3/30, and 3/31. There was no evidence QC had been performed. 3. Interview on 4/28/22 at 2 PM with the laboratory consultant and the lead technologist confirmed QC had not been performed each day of patient testing.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on new instrument and test method verification study review, lack of documentation, and staff interview, the laboratory director failed to ensure the study included the verification of precision and reportable range and failed to confirm the manufacturer's normal values were appropriate for the laboratory's patient population for 1 of 4 new test verification studies reviewed (Alere D-dimer). Since implementation the laboratory had performed 136 patient tests. Refer to D5421.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on procedure manual review, lack of documentation and staff interview, the laboratory director failed to ensure the laboratory had established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic systems. The findings were: 1. The laboratory procedure manual failed to include a quality assurance plan which included the items the laboratory reviews, the frequency of review, and the method the laboratory used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, specimen labeling, storage, and transportation. c. Analytic tasks which include review of quality control, instrument preventive maintenance, reagent replacement and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview with the laboratory consultant and lead technologist on 4/29/22 at 2 PM revealed the laboratory had not established a quality assessment plan.