Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453138	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Western Plains Medical Heights	**Street Address, City, State** 100 Ross Blvd Suite 2a, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) from the provider American Proficiency Institute (API) performed after November 8, 2018 until date of survey and interview, the laboratory director (LD) or designee failed to attest on eight of eight reveiwed events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. A review of eight of eight proficiency testing events from November 8, 2018 to January 8, 2020 year revealed that attestation statement did not contain the signature of the LD or designee. a. API 2018 Chemistry Core, 3rd Event b. API 2018 Hematology/Coagulation, 3rd Event c. API 2019 Hematology/Coagulation, 1st, 2nd, and 3rd Events d. API 2019 Chemistry Core, 1st, 2nd, and 3rd Events 2. Interview with Testing Personnel (TP) #1 on January 8, 2020 at 11:20 a.m. confirmed, the LD or designee failed to attest on eight of eight reveiwed events that proficiency testing samples were handled in the same manner as patient samples.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on the lack of documentation and interview, the laboratory failed to assess competency of the technical consultant (TC). Findings: 1. No competency documentation for the TC was available at the time of survey. 2. Interview with TP#1 on January 8, 2020 at 10:40 a.m. confirmed, the laboratory failed to assess competency of the TC.
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 documentation for the Sysmex XN-4 hematology analyzer and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population. Findings: 1. Review of the verification documentation of the Sysmex XN-4 hematology analyzer , S/N 11190, installed July 9, 2019, for the analytes: White Bloodcell Differential, Red Bloodcell Count, Hemoglobin, Hematocrit, White Bloodcell Count, and Platelet testing showed no verification of normal values. 2. Interview with TP #1 on January 8, 2020 at 12:10 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population.