Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0872258	05/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Primary Care Partners - Hmc	720 Medical Center Drive, Newton, 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 in 2020 and 2021 and interview with Chief Operations Officer (COO) revealed that the LD or approved designee failed to attest on seven events that proficiency testing samples were handled in the same manner as patient samples at time of survey. Findings: 1. Review of the attestation pages for PT from API revealed no signature of the LD or approved designee was present on API 2020 events: a. Chemistry Core 2nd Event b. Hematology / Coagulation 3rd Event c. Microbiology 2nd Event d. Chemistry Miscellaneous 1st Event 2. Review of the attestation pagers for PT from API revealed no signature of the LD or approved designee was present on API 2021 events: a. Hematology / Coagulation 2nd Event b. Microbiology 3rd Event c. Chemistry Miscellaneous 2nd Event 2. Interview with the COO on 5/17/2022 at 11:50 a.m. confirmed, the laboratory director (LD) or approved designee failed to attest on seven events that proficiency testing samples were handled in the same manner as patient samples at time of survey.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on review of approved reference ranges in the laboratory "Reference Range" procedure manual and interview with the Chief Operations Officer (COO), the laboratory failed to ensure the test report included pertinent age and gender normal ranges as determined by the laboratory "Reference Range" policy at time of survey. Findings: 1. Review of the patient reports from the Laboratory Information System (LIS) revealed thirteen parameters for normal ranges did not correctly match those reference ranges for the complete blood count (CBC) test in the laboratory "Reference Range" procedure manual. LIS patient report: (Unisex/No age specifics) WBC 5.0-10.0 10^3/uL RBC 4.7-6.1 10^6/uL HGB 14.0-18.0 g/dL HCT 42.0-52.0 % MCV 80.0-95.0 fL MCH 27.0-31.0 pg MCHC 32.0-36.0 g/dL PLT 150-450 10^3/uL NEUT% 55.0-70.0 % LYM% 20.0-40.0 % MON% 2.0-8.0 % EOS% 1.0-4.0 % BAS% 0.5-1.0 % Procedure Manual Parameters: (Female Adult >21 y/o) (Male Adult >21 y/o) WBC 3.98-10.04 10^3/uL 4.23-9.07 10^3/uL RBC 3.93-5.22 10^6/uL 4.63-6.08 10^6/uL HGB 11.2-15.7 g/dL 13.7-17.5 g/dL HCT 34.1-44.9 % 40.1-51.0 % MCV 79.4-94.8 fL 79.0-92.2 fL MCH 25.6-32.2 pg 25.7-32.2 pg MCHC 32.2-35.5 g /dL 32.3-36.5 g/dL PLT 182-369 10^3/uL 163-337 10^3/uL NEUT% 34.0-71.1 % 34.0-67.9 % LYM% 19.3-51.7 % 21.8-53.1 % MON% 4.4-12.5 % 5.3-12.2 % EOS% 0.7-5.8 % 0.8-7.0 % BAS% 0.1-1.2 % 0.2-1.2 % 2. Interview with COO on 5/17/2022 at 11:50 a.m. confirmed, the laboratory failed to ensure the correct reference ranges approved in the "Reference Range" procedure manual were in correlation with the LIS patient report.