Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2109478	07/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Premier Plus Urgent Care	1616 S Mustang Road, Yukon, OK	

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
D0000	The recertification survey was performed on 07/05/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director for two of five events reviewed during 2021, 2022, and to date in 2023. Findings include: (1) A review of the third 2021; first, second, and third 2022; and first 2023 Hematology proficiency testing records identified the following for two of five events: (a) Nonchemistry Q1 2022 Event - The attestation statement had not been signed by the laboratory director; (b) Nonchemistry M1 2023 Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory manager who stated on 07/05/2023 at 11: 55 am, the attestation statements had not been signed by the laboratory director.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing six of 15 new lot numbers of Hematology QC (quality control) materials during the review period of July 2022 through June 2023. Findings include: (1) On 07/05/2023 at 10:50 am, the laboratory manager stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex pocHi-100i analyzer; (b) The laboratory used the manufacturer's stated ranges to evaluate QC results; (c) When new lot numbers of control materials were put into use the laboratory verified the stated value of the control materials by testing them twice a day for five days before putting into use. (2) A review of the manufacturer's instructions contained in the "Sysmex pocH-i Hematology Analyzer Implementation Manual" under section D titled, "New Lot of Quality Control Material" stated, "Upon receipt of a new lot of control material, it is recommended that controls of the new lot be run in parallel with the current lot for ten (10) replicates over multiple days"; (3) A review of the implementation records for new lots of QC materials from October 2022 through June 2023 identified the manufacturer's instructions had not been followed for six of 15 lots numbers as follows: (a) Low Abnormal Control lot #21940710, Normal Control lot #21940711, and High Abnormal Control lot # 21940712 - Put into use on 10/20/2022. Although the laboratory had tested each level of QC material for ten replicates, they were all tested on 10/19/2022 instead of multiple days; (b) Low Abnormal Control lot #23620710, Normal Control lot #23620711, and High Abnormal Control lot # 23620712 - Put into use on 01/14/2023. Although the laboratory had tested each level of QC material for ten replicates, they were all tested on 01/13/2023 instead of multiple days. (4) The records were reviewed with the laboratory manager who stated on 07/05/2023 at 12:50 pm, the laboratory had not followed the manufacturer's instructions for implementing new lot number of QC material as shown above.