Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2109478	05/13/2019
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 05/13/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the clinic manager/testing person #1 at the conclusion of the survey.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of records and interview with the clinic manager/testing person #1, the laboratory failed to test proficiency testing in the same manner as patient specimens. Findings include: (1) During the survey, the surveyor reviewed Hematology proficiency testing records for the third 2017, first 2018, second 2018, third 2018, and first 2019 events. The records indicated the laboratory had not tested proficiency testing samples in the same manner as patient specimens for 4 of 5 events as follows: (a) First 2018 Event - 5 of 5 specimens had been tested in duplicate: (i) Specimen 1 - Initially tested on 03/05/18 at 05:52 pm. The sample was retested on 03 /05/18 at 06:18 pm; (ii) Specimen 2 - Initially tested on 03/05/18 at 06:18 pm. The sample was retested on 03/05/18 at 06:21 pm; (iii) Specimen 3 - Initially tested on 03 /05/18 at 06:24 pm. The sample was retested on 03/05/18 at 06:26 pm; (iv) Specimen 4 - Initially tested on 03/05/18 at 06:45 pm. The sample was retested on 03/05/18 at 06:49 pm; (v) Specimen 5 - Initially tested on 03/05/18 at 06:58 pm. The sample was

	retested on 03/05/18 at 07:01 pm. (b) Second 2018 Event - 3 of 5 specimens had been tested in duplicate: (i) Specimen 7 - Initially tested on 05/24/18 at 04:25 pm. The sample was retested on 05/24/18 at 04:26 pm; (ii) Specimen 8 - Initially tested on 05 /24/18 at 04:29 pm. The sample was retested on 05/24/18 at 04:32 pm; (iii) Specimen 10 - Initially tested on 05/24/18 at 04:37 pm. The sample was retested on 05/24/18 at 04:41 pm. (c) Third 2018 Event - 5 of 5 specimens had been tested in duplicate: (i) Specimen 11 - Initially tested on 10/23/18 at 12:06 pm. The sample was retested on 10 /23/18 at 12:10 pm; (ii) Specimen 12 - Initially tested on 10/23/18 at 12:13 pm. The sample was retested on 10/23/18 at 12:29 pm; (iii) Specimen 13 - Initially tested on 10 /23/18 at 12:39 pm. The sample was retested on 10/23/18 at 02:09 pm; (iv) Specimen 14 - Initially tested on 10/23/18 at 02:13 pm. The sample was retested on 10/23/18 at 02:16 pm; (v) Specimen 15 - Initially tested on 10/23/18 at 02:19 pm. The sample was retested on 10/23/18 at 02:23 pm. (d) First 2019 Event - 5 of 5 specimens had been tested in duplicate: (i) Specimen 1 - Initially tested on 02/13/19 at 04:24 pm. The sample was retested on 02/13/19 at 05:01 pm; (ii) Specimen 2 - Initially tested on 02 /13/19 at 05:08 pm. The sample was retested on 02/13/19 at 05:05 pm; (iii) Specimen 3 - Initially tested on 02/13/19 at 05:14 pm. The sample was retested on 02/13/19 at 05:16 pm; (iv) Specimen 4 - Initially tested on 02/13/19 at 05:19 pm. The sample was retested on 02/13/19 at 05:23 pm; (v) Specimen 5 - Initially tested on 02/13/19 at 05: 25 pm. The sample was retested on 02/13/19 at 05:29 pm. (2) The surveyor reviewed the records with the clinic manager/testing person #1 and asked if patient specimens were routinely tested in duplicate as the above proficiency specimens had been tested. The clinic manager/testing person #1 stated the following to the surveyor: (a) Patient specimens were routinely tested one time unless they met the criteria to repeat (i.e., critical values); (b) The results from the proficiency testing samples (above) did not meet the criteria to repeat, and therefore had not been tested using the laboratory's routine methods for patient testing.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the clinic manager/testing person #1, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) During the survey, the surveyor reviewed 2017, 2018, and 2019 Hematology proficiency testing records. The following failures were identified, for which corrective action documentation could not be located: (a) Third 2017 Event (i) RBC (Red Blood Cell) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (ii) Hemoglobin - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (iii) Hematocrit - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) The surveyor asked the clinic manager/testing person #1 if corrective action had been taken for the failures. After reviewing the records, the clinic manager/testing person #1 stated corrective action had not been taken for the failures.
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 clinic manager/testing person #1, the laboratory failed to follow the manufacturer's instructions for verifying flagged results. Findings include: (1) At the beginning of the survey, the clinic manager/testing person #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex pocH 100i analyzer; (b) Manual differential testing was not performed in house. If a manual differential was required, the specimen would be sent to a reference laboratory. (2) Later during the survey, the surveyor reviewed the manufacturer's instructions for verifying flags obtained on the analyzer. For T2 flags, the instructions stated, "Aged sample, incomplete lysing of red blood cells, etc., causing the last two WBC populations in the WBC-Histogram not to be separated, presence of CML or other immature granulocytes." In addition, the instructions stated, "Check Smear" and "Warm Sample and Repeat Analysis"; (3) The surveyor randomly reviewed 3 patient records which contained T2 flags from CBC testing performed between 01/01/18-12 /31/18. For 3 of 3 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the T2 flags. The findings for the 3 records were: (a) Patient testing was performed on 02/04/18, with T2 flags obtained next to MXD% and NEUT%; (b) Patient testing was performed on 02/18/18, with T2 flags obtained next to MXD% and NEUT%; (c) Patient testing was performed on 07/14/18, with T2 flags obtained next to MXD% and NEUT%. (4) The surveyor reviewed the records with the clinic manager/testing person #1, who stated the flags obtained for the above 3 patients had not been verified as required by the manufacturer.
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 a review of records, manufacturer's instructions, and interview with the clinic manager/testing person #1, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the clinic manager/testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex pocH 100i analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records from January 2018 through April 2019 and identified the range, used by the laboratory to determine if humidity readings were acceptable, was 20-80%. In addition, documented humidity readings were less than 30% for 6 of 16 months as follows: (a) January 2018 - 22 of

	31 humidity readings were documented as less than 30% (days 01,02,03,04,05,06,12,13,14,15,16,17,18,19,23,24,25,26,28,29,30,31); (b) February 2018 - 13 of 27 humidity readings were documented as less than 30% (days 02,03,04,05,06,07,08,09,10,11,12,13,21); (c) December 2018 - 1 of 19 humidity readings was documented as less than 30% (day 01); (d) January 2019 - 3 of 31 humidity readings were documented as less than 30% (days 25,29,31); (e) February 2019 - 2 of 28 humidity readings were documented as less than 30% (days 18,28); (f) March 2019 - 5 of 31 humidity readings were documented as less than 30% (days 02,03,05,06,07). (4) The surveyor reviewed the records with the clinic manager /testing person #1, who stated the acceptable range documented on the laboratory humidity logs was not acceptable and the humidity of the laboratory had been maintained below 30% as indicated above.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the clinic manager/testing person #1, the laboratory director failed to provide overall supervision and effective direction over the operation and administration of the laboratory. Findings include: (1) At the beginning of the survey, the clinic manager/testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex pocH 100i analyzer; (2) Later during the survey, the surveyor reviewed quality control, maintenance, temperature, and humidity records for the CBC testing performed in the laboratory from 01/01/18 through 04/30/19; (3) There was no evidence (i.e, signatures, dates, notes, etc.) in the records to demonstrate review by the laboratory director; (4) The surveyor reviewed the records with the clinic manager/testing person #1 who stated that, although the laboratory director reviewed the records, the review had not been documented.