

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2278351	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Premier Plus Urgent Care	Street Address, City, State 12000 Charleston Way, 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 initial survey was performed on 11/20/2024. 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.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to utilize the demonstrated reportable range for Hemoglobin for one of one new test method. Findings include: (1) On 11/20/2024 at 10:30 am, the laboratory manager stated the laboratory began performing CBC (Complete Blood Count) testing using the Sysmex POCH-100i analyzer on 08/22/2024; (2) A review of the performance specification records identified the laboratory had demonstrated a reportable range for Hemoglobin of 0-21.2 g/dL; (3) Interview with the laboratory manager on 11/20/2024 at 11:15 am, confirmed the laboratory was using the manufacturer's reportable range of 0.1-25 g/dL instead of the range that had been demonstrated by the laboratory.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p>

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

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 patient test reports included either the patient's name and identification number, or a unique patient identifier and identification number for one of one patient CBC (Complete Blood Count) report reviewed. Findings include: (1) On 11/20/2024 at 10:30 am, the laboratory manager stated CBC testing was performed using the Sysmex POCH-100i analyzer; (2) A review of one patient report with testing performed on 08/22/2024 identified the report did not include a patient name or identification number (only the patient's medical record number which is a unique patient identifier was on the report); (3) The report was reviewed with the laboratory manager who stated on 11/20/2024 at 11:45 am, the report did not include a second patient identifier.