Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0669657	02/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Primed Physicians Laboratory	948 Patterson Road, Dayton, OH	

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
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 record review, and an interview with the General Supervisor (GS), the laboratory failed to follow their written policy and procedure to assess competency of the GS, as specified in the personnel requirements in subpart M. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of the laboratory's "Competency Assessment" policy and procedure failed to find a written policy and procedure to assess competency of the GS based on the federal regulatory responsibilities of that position. 2. Review of the laboratory's Competency Assessment documentation found the lab failed to assess the GS for competency based on the federal regulatory responsibilities of that position. 3. An interview with the GS, on 2/25/19 at 1:26 pm, confirmed that the lab failed to to assess the GS for competency based on the federal regulatory responsibilities of that position.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Item I: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to include, in the 'preparing and staining peripheral blood smears for examination' policies and procedures, the quality control procedures for the intended reactivity of the Hemacolor stain and the corrective action to take when QC results fail to meet the laboratory's criteria for acceptability. All patients tested at this laboratory have the potential to affected. Findings Include: 1. Review of the laboratory's 'preparing and staining peripheral blood smears for examination' policy and procedure failed to find instructions for quality control procedures for the intended reactivity of the Hemacolor stain and the corrective action to take when QC results fail to meet the laboratory's criteria for acceptability. 2. Review of the laboratory's quality control records for the Hemacolor stain, failed to find instructions for quality control procedures for the intended reactivity of the Hemacolor stain and the corrective action to take when QC results fail to meet the laboratory's criteria for acceptability. 3. An interview with the GS, on 2/25/19 at 1:52 pm, confirmed that procedure for 'preparing and staining peripheral blood smears for examination' failed to include instructions for quality control procedures for the intended reactivity of the Hemacolor stain and the corrective action to take when QC results fail to meet the laboratory's criteria for acceptability. Item II: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to include reference interval units of measure in the procedure manual as instruction for reporting patient test results. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of the policy and procedure 'Normal Reference Ranges for PriMed Laboratory' found no reference range unit of measure as instruction for reporting patient results. 2. An interview with the GS, on 2/25/19 at 1:59 pm, confirmed that the policy and procedure 'Normal Reference Ranges for PriMed Laboratory' contained no reference range unit of measure as instruction for reporting patient results.
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 record review and an interview with the General Supervisor (GS), the laboratory failed to establish and verify reference intervals, appropriate for the patient population, for Mean Corpuscular Volume (MCV) for patients over fourteen years of age before reporting patient results. All patients over the age of fourteen tested for MCV have the potential to be affected. Findings include: 1. Review of the laboratory's established and verified reference ranges found the MCV reference range and corresponding age as follows: "0-1M 102-115 1M-2YR 72-88 2YR-8YR 76-90 8YR-14YR 78-95" 2. Review of sixteen MCV test reports found ten patients tested that were over the age of fourteen. Patient #1: age 28 Patient #2: age 44 Patient #3: age 16 Patient #4: age 58 Patient #5: age 74 Patient #6: age 48 Patient #7: age 61 Patient #8: age 25 Patient # 9: age 45 Patient #9: age 74 Patient #10: age 64 3. An interview with the GS, on 2/25/19 at 2:17 pm, confirmed that the lab failed to establish and verify reference intervals for MCV for patients over fourteen years of age prior to reporting patient results.
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: Item I: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to report the correct reference interval for potassium, for ten out of fourteen patients reviewed, as determined by the laboratory and approved by the Laboratory Director. Findings include: 1. Review of the laboratory's established reference ranges listed the potassium reference range and corresponding age: "1D-8WK 3.2-5.5 8WK-2 YR 3.5-5.6 2YR-1YR 3.3-4.6 >10YR 3.6-5.0" 2. Review of fourteen of the laboratory's patient test reports from 2017 through 2019, found the following reported reference intervals for potassium, and corresponding age: Patient #1, age 28: 3.60-5.30 mmol/L Patient #2, age 44: 3.60-5.30 mmol/L Patient #3, age 16: 3.60-5.30 mmol/L Patient #4, age 74: 3.60-5.30 mmol/L Patient #5, age 48: 3.60-5.30 mmol/L Patient #6, age 61: 3.60-5.30 mmol/L Patient #7, age 25: 3.60-5.30 mmol /L Patient #8, age 45: 3.60-5.30 mmol/L Patient #9, age 74: 3.60-5.30 mmol/L Patient #10, age 64: 3.60-5.30 mmol/L 3. An interview with GS, on 2/25/19 at 2:10 pm, confirmed that the lab failed to report the correct reference interval for potassium on ten out of fourteen reviewed patients. Item II: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to report the correct reference interval for Mean Corpuscular Volume (MCV) , for one out of fourteen patients reviewed, as determined by the laboratory and approved by the Laboratory Director. Findings include: 1. Review of the laboratory's established reference ranges listed the MCV reference range and corresponding age: "0-1M 102-115 1M-2YR 72-88 2YR-8YR 76-90 8YR-14YR 78-95" 2. Review of fourteen of the laboratory's patient test reports from 2017 through 2019, found the following reported reference interval for MCV, and corresponding age for one patient: Patient #1, age 14: 80-100 fL 3. An interview with GS, on 2/25/19 at 2:10 pm, confirmed that the lab failed to report the correct reference interval for MCV on one out of fourteen reviewed patients.