

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455307	(X3) Date Survey Completed 12/17/2024
Name of Provider or Supplier Physicians Laboratory Services Inc D/B/A	Street Address, City, State 7441 O Street Suite 100, Lincoln, NE	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of procedure manual (Refer to 5407), not following manufacturer's instructions (Refer to 5411), not establishing performance specifications (Refer to 5423), and review of quality control records (Refer to 5447) the laboratory failed to monitor and evaluate the overall quality of testing.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with the technical supervisor the laboratory failed to have the "Relion Prime Blood Glucose Monitoring System Performing a Blood Glucose Test" signed by the laboratory director. 1. Review of the laboratory's "Relion Prime Blood Glucose Monitoring System</p>

Performing a Blood Glucose Test" procedure revealed the procedure was not signed by the lab director. 2. Interview with the technical supervisor on 12/17/2024 at 1:42 PM, confirmed the laboratory could not locate the signed procedure.

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 review of manufacturer's instructions and interview with technical supervisor the laboratory failed to follow manufacturer's instructions for the Relion Prime glucose meter testing performed on 1/2/2024 - 12/17/2024. Findings are: 1. Review of the manufacturer's instruction manual for the Relion Prime glucose meter states to, "Use only fresh capillary whole blood samples for testing." 2. The laboratory's "Relion Prime Blood Glucose Monitoring System Performing a Blood Glucose Test" procedure indicates "specimen requirement - EDTA whole blood is collected in tandem with SST for fasting specimen only." 3. Interview with the technical supervisor on 12/17/2024 at 1:42 PM, confirmed the laboratory uses venous whole blood on the Relion Prime glucose meter. 4. Review of the manufacturer's instruction manual for the Relion Prime glucose meter states, "The system is intended to be used by a single person and should not be shared." 5. Interview with the technical supervisor on 12/17/2024 at 1:42 PM, confirmed the laboratory uses one Relion Prime glucose meter for multiple patient use.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on surveyor observation and interview with the technical supervisor the laboratory failed to establish performance specifications on the Relion Prime glucose meter used for testing on 1/2/2024 - 12/17/2024. 1. Tour of the laboratory revealed a glucose meter in the chemistry area of the laboratory. Blood glucose meter testing was not listed on the laboratory's list of tests performed. 2. Interview with the technical supervisor on 12/17/2024 at 1:42 PM confirmed the laboratory uses the Relion Prime glucose meter to test fasting venous whole blood specimens on patients having a glucose tolerance test. 3. Interview with the technical supervisor on 12/17/2024 at 1:

42 PM, confirmed the laboratory failed to establish performance specifications for the Relion Prime glucose meter.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records and confirmed by the technical supervisor the laboratory failed to perform two levels of external QC each day of patient testing on the Relion Prime glucose meter for fifty-two out of fifty-two days of patient testing from 1/2/2024 - 12/17/2024. 1. The laboratory used the Relion Prime glucose meter to test fasting whole blood specimens on patients that are having a glucose tolerance test. 2. The laboratory failed to perform two levels of external QC on fifty-two out of fifty-two days of patient testing from 1/2/2024 - 12/17/2024. 3. Interview with the technical supervisor on 12/17/2024 at 1:42 PM, confirmed the laboratory failed to perform two levels of external QC each day of patient testing.