

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2164792	(X3) Date Survey Completed 09/01/2026
Name of Provider or Supplier Precision Labs Llc	Street Address, City, State 15320 Conway Rd, Chesterfield, MO	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the Thermo Fisher Scientific KingFisher Flex operator's guide, lack of polymerase chain reaction (PCR) laboratory temperature logs, review of patient results and interview with the technical supervisor (TS) #2, the laboratory failed to ensure the room temperature and humidity was monitored and documented as required by the manufacturer in 2024, 2025 and to date September 2, 2026. Findings: 1. Review of the Thermo Fisher Scientific KingFisher Flex operator's guide states "operating conditions (indoor use) +5 degrees Celsius to +40 degrees Celsius; maximum relative humidity 80% for temperatures up to 31 degrees Celsius decreasing linearly to 50% relative humidity at 40 degrees Celsius; Indoor use only". 2. Lack of PCR laboratory temperature logs where the Thermo Fisher Scientific KingFisher Flex is located showed the laboratory failed to document room temperature and humidity in 2024, 2025 and to date September 2, 2026. 3. Review of patient results showed the laboratory performs approximately 19,200 PCR patient tests per year. 4. Interview with the technical supervisor (TS) #2 on September 2, 2026, at 11:00 AM confirmed the laboratory failed to ensure the room temperature and humidity was maintained as required by the manufacturer.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the polymerase chain reaction (PCR) laboratory safety hood, review of patient results and interview with the technical supervisor (TS) #2, the laboratory failed to define, perform and document maintenance for the laboratory safety hood in 2024, 2025 and to date September 2, 2026. Findings: 1. Observation of the PCR laboratory safety hood showed no documentation of maintenance for the laboratory safety cabinet in 2024, 2025 and to date September 2, 2026. 2. Review of patient results showed the laboratory performs approximately 19,200 PCR patient tests per year. 3. Interview with the TS #2 on September 2 at 11:00 AM confirmed the laboratory failed to perform and document maintenance for the PCR laboratory safety hood.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Sysmex CA-500 analyzer quality control (QC), review of patient results and interview with the office manager, the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) for two of forty patient testing days in April and May 2026. Findings: 1. Review of laboratory procedure "Prothrombin Time (PT) Seconds" states, "Controls should be tested at the initiation of testing, upon reagent changes, and at least once each 8-hour shift." 2. Review of Sysmex CA-500 analyzer QC for April and May 2026 showed two levels of prothrombin time (PT) QC was not performed on April 6, 2026, and May 8, 2026. 3. Review of patient results showed 11 prothrombin time (PT) patient results were reported on April 6, 2026, and 3 prothrombin time (PT) patient results were reported on May 8, 2026 without QC being performed. 4. Interview with the office manager on September 1, 2026, at 12:00 PM confirmed the laboratory failed to perform two levels of prothrombin time (PT) QC each 8 hours of operation.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) procedure, 2026 PT records, and interview with the office manager, the laboratory director failed to ensure appropriate

	staff evaluated the laboratory's performance on PT results for 3 of 7 events in 2026. Findings: 1. Review of "Proficiency Testing Procedure" states "5.6 Review of PT Results: #2 Results shall be evaluated for: acceptable performance, unacceptable performance, trends or repeated marginal performance, clerical/reporting errors, instrument or reagent-related issues, method-related issues. 6. Unacceptable PT Performance: #6 Document the investigation, findings, corrective actions and follow-up". 2. Review of 2026 PT records showed no corrective action documentation was available to show the laboratory investigated unacceptable PT results on the following performance evaluations: College of American Pathologists (CAP) GH5-A 2026 Hemoglobin A1C, Accuracy-Based (GH5) CAP C-A 2026 General Chemistry /Therapeutic Drugs (C3) CAP FH9-A 2026 Hematology Auto Differentials, FH9 (FH9) 3. Review of 2026 PT records showed no corrective action documentation was available to show the laboratory investigated ungraded PT results on the following performance evaluations: CAP C-A 2026 General Chemistry/Therapeutic Drugs (C3) CAP FH9-A 2026 Hematology Auto Differentials, FH9 (FH9) 4. Interview with office manager on September 2, 2026 at 12:00 PM confirmed the laboratory director failed to ensure appropriate staff evaluated the laboratory's performance on PT results.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) education and experience documents, review of patient results and interview with the office manager, the laboratory director failed to ensure one of one testing personnel had the appropriate education and experience to qualify to perform high complexity testing prior to the testing personnel performing high complexity testing from August 2024 to date September 1, 2026. Findings: 1. Review of testing personnel (TP) education and experience documents showed testing personnel # 2 failed to have the appropriate education and experience to qualify to perform high complexity testing. 2. Review of patient results showed testing personnel # 2 performed 22,750 high complexity tests from August 2024 to date September 1, 2026. 3. Interview with the office manager on September 1, 2026, at 12:00 PM confirmed the laboratory director failed to ensure testing personnel had the appropriate education and experience to qualify to perform high complexity testing.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of CMS-209 form, review of laboratory testing personnel (TP)

	competency and training documents, review of patient results and interview with the office manager, the technical supervisor (TS) failed to evaluate and document the competency/performance of two of two testing personnel (TP) at least annually during the employee's first year of hire. Findings: 1. Review of the laboratory's submitted CMS-209 form showed testing personnel # 2 required an annual competency evaluation in August 2025 and testing personnel # 3 required an annual competency evaluation in July 2026. 2. Review of laboratory testing personnel competency and training documents showed the TS failed to evaluate and document annual competency /performance for TP # 2, and TP # 3 performing patient testing. 3. Review of patient results showed the laboratory performs approximately 201,544 patient tests per year. 4. Interview with the office manager on September 1, 2026, at 12:00 PM confirmed the TS failed to evaluate and document annual competency/performance evaluations.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of education and experience documents and interview with the office manager, one of one testing personnel performing high complexity testing failed to meet the academic qualifications required to perform high complexity testing (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of education and experience documents, review of patient results and interview with the office manager, the laboratory failed to ensure one of one testing personnel performing high complexity testing met the qualification requirements required to perform high complexity testing. Findings: 1. Review of education and experience documents showed testing personnel # 2 failed to meet the qualification requirements required to perform high complexity testing. Testing personnel # 2 has been performing high complexity testing since August 2024. 2. Review of patient results showed testing personnel # 2 performed 22,750 high complexity tests from August 2024 to date September 1, 2026. 3. Interview with the office manager on September 1, 2026, at 12:00 PM confirmed the laboratory failed to ensure testing personnel met the qualification requirements required to perform high complexity testing.