Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2267171	06/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Peak Clinical Diagnostics Llc	2600 S Parker Road Suite 2-125, Denver, CO	

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	Based on an on-site initial certification survey conducted on June 17, 2025, through June 23, 2025, the following condition level deficiencies were cited for Peak Clinical Dignostics, LLC in Aurora, Colorado: 493.1250 Condition: Analytic systems; and 493. 1459 Condition: Laboratories performing high complexity testing; general supervisor
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (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 proficiency testing (PT) records, the laboratory's policies and procedures manual, an interview with the general supervisor (GS), and technical supervisor 2 (TS2), the laboratory failed to test their hematology PT specimens in the same manner it tests routine patient specimens. Findings include: 1. A review of the laboratory's Pentra XL hematology instrument printouts accompanying the American Proficiency Institute (API) PT records for event 1 of 2025 in the specialty of hematology revealed that the laboratory ran all 5 of the 2025 hematology event 1 PT specimens on both of the laboratory's Pentra XL instruments. 2. A review of the laboratory's PT policy stated that " ... proficiency testing specimens are to be handled and analyzed exactly as patient specimens ... these specimens should not be run multiple times or on multiple instruments." 3. An interview with the GS, on June 17, 2025, at approximately 11:00 AM, confirmed that the laboratory did not treat the 2025

	hematology event 1 PT specimens like patient specimens by running all 5 of the 2025 hematology event 1 PT specimens on both of the laboratory's Pentra XL instruments, against the laboratory's PT policy stating: " ... proficiency testing specimens are to be handled and analyzed exactly as patient specimens ... these specimens should not be run multiple times or on multiple instruments." 4. An interview with TS2, on June 17, 2025, at approximately 11:05 AM, confirmed that the laboratory did not treat the 2025 hematology event 1 PT specimens like patient specimens by running all 5 of the 2025 hematology event 1 PT specimens on both of the laboratory's Pentra XL instruments, against the laboratory's PT policy stating: " ... proficiency testing specimens are to be handled and analyzed exactly as patient specimens ... these specimens should not be run multiple times or on multiple instruments."
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on the number of the deficiencies cited herein, the laboratory is not in compliance with the Condition: Analytic Systems. The laboratory failed to monitor the quality of the water produced by its water purification system; failed to monitor the temperature and humidity of each room where patient testing is performed; failed to calibrate its thermometers used in refrigerators and freezers annually (See D5413), the laboratory failed to verify the manufacturer's stated reference intervals (normal values) were appropriate for the laboratory's patient population (see D5421), failed to verify the acceptable ranges and means of liquid assayed chemistry quality control materials (see D5469), failed to establish a system to evaluate at least twice a year the relationship between test results from their Horiba Pentra XL hematology instruments (see D5775), failed to establish a system to identify and assess patient test results that are inconsistent with previous patient results or are inconsistent with other test parameters (see D5777), and failed to document the corrective actions taken when the laboratory's chemistry instrument was operating outside of the established performance specifications (see D5781).
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 a review of the laboratory's instrument maintenance logs, environmental monitoring logs, policies and procedures manual, instrument manufacturer specifications, thermometer calibration logs, direct observation of the laboratory, and an interview with the general supervisor (GS), technical supervisor 1 (TS1) and technical supervisor 2 (TS2), the laboratory failed to monitor and document water quality produced by the laboratory's purification system, failed to have a means to monitor room temperature and humidity in each room of the laboratory where testing is performed, and failed to follow its policy to calibrate thermometers used in refrigerators and freezers annually. Findings include: 1. A review of the laboratory's instrument maintenance logs for the Beckman-Coulter AU480 chemistry instrument revealed that the laboratory failed to document the water quality produced by the laboratory's water purification system feeding the AU-480 instrument daily. 2. A review of the Beckman-Coulter AU-480 operating requirements stated the water quality feeding the AU-480 chemistry instrument must be less than 2.0 S/cm or less for each day that patient testing occurs. 3. A direct observation of the laboratory, on June 17, 2025, at approximately 2:00 PM, revealed that there was no means of monitoring the room temperature or humidity in each room the laboratory where patient testing was performed. 4. A review of the laboratory's environmental monitoring logs revealed the laboratory was recording the room temperature and humidity in each room that patient testing is performed, but did not have a thermometer/hydrometer in each room that patient testing is performed. 5. A direct observation of the laboratory, on June 17, 2025, at approximately 2:00 PM revealed several windows open in the laboratory where patient testing was being performed, but no means to monitor the room's temperature and humidity. 6. An interview with the GS, on June 17, 2025, at approximately 2:15 PM, confirmed that the laboratory had discarded its thermometer and hydrometer in the main specimen processing room the morning of the survey due to its calibration being expired. The GS also confirmed, on June 17, 2025, at approximately 2:15 PM, that the room temperature and humidity for the main specimen processing room was the temperature recorded for all other rooms in the laboratory that patient testing performed. 7. A review of the laboratory's policies and procedures manual revealed that the laboratory is required to calibrate and document the calibration of thermometers used to monitor refrigerator or freezer temperatures to a NIST-traceable thermometer annually. 8. A review of the laboratory's thermometer calibration logs, on June 17, 2025, at approximately 3:00 PM, revealed the laboratory had failed to calibrate its refrigerator and freezer thermometers to a NIST-traceable thermometer annually as required by their policy. 9. An interview with TS1 and TS2, on June 17, 2025 at approximately 3:00 PM, confirmed that the laboratory failed to monitor and document water quality produced by the laboratory's purification system, failed to have a means to monitor room temperature and humidity in each room of the laboratory where testing is performed, and failed to follow its policy to calibrate thermometers used in refrigerators and freezers annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 a review of the laboratory's verification of performance specifications documents for their Horiba Pentra XL hematology instruments, and an interview with technical supervisor 2 (TS2), the laboratory failed to verify the manufacturer's reference intervals (normal values), are appropriate for the laboratory's patient population. Findings include: 1. A review of the laboratory's verification of performance specifications documents for their Horiba Pentra XL hematology instruments, the laboratory failed to verify that the manufacturer's stated reference intervals (normal values) were appropriate for the laboratory's patient population prior to releasing patient test results. 2. An interview with TS2, on June 18, 2025 at approximately 12:15 PM, confirmed that the laboratory had failed to verify that the manufacturer's stated reference intervals (normal values) were appropriate for the laboratory's patient population prior to releasing patient test results.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, a review of the laboratory's chemistry QC logs, and an interview with technical supervisor 1 (TS1) and technical supervisor 2 (TS2), the laboratory failed to verify the acceptable ranges and means stated by the manufacturer of the laboratory's chemistry quality control (QC) material before being put into use by the laboratory. Findings include: 1. A review of the laboratory's policies and procedures manual stated the laboratory must verify the acceptable ranges, and means stated by the laboratory's QC manufacturer, Randox, for their liquid assayed chemistry controls by running the new lot of QC material for at least 10 days and confirming the laboratory's ranges and means fall within the manufacturer's acceptable ranges and means. 2. A review of the laboratory's QC logs revealed that the laboratory implemented a new lot of Randox liquid assayed chemistry QC in April of 2025, but failed to document the verification of the manufacturer's stated acceptable ranges and means for their Randox liquid assayed chemistry QC materials before being put into use by the laboratory. 3. An interview with TS1 and TS2 on June 17, 2025 at approximately 1:30 PM, confirmed that the laboratory failed to follow its policy and procedure to verify the acceptable ranges and means stated by the laboratory's QC manufacturer, Randox, for their liquid assayed chemistry QC, and that the laboratory failed to document the verification of those acceptable values and means prior to implementing a new lot of Randox liquid assayed chemistry QC material in April of 2025.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with technical supervisor 2 (TS2), the laboratory failed to establish a system to evaluate at least twice a year the relationship between test results from their Horiba Pentra XL hematology instruments. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory did not establish a system to evaluate at least twice a year the relationship between test results from their Horiba Pentra XL hematology instruments. 2. An interview with TS2 on June 18, 2025, at approximately 2:30 PM, confirmed that the laboratory failed to establish a system to evaluate at least twice a year the relationship between test results from their Horiba Pentra XL hematology instruments.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with technical supervisor 2 (TS2), the laboratory failed to establish a system to identify and assess patient test results that are inconsistent with previous patient results or are inconsistent with other test parameters. Findings include: 1. Based on a review of the laboratory's policies and procedures manual for hematology and chemistry testing, the laboratory failed to establish a system to identify and assess patient test results that are inconsistent with previous patient results or are inconsistent with other test parameters. 2. An interview with TS2 on June 18, 2025, at approximately 2:30 PM, confirmed that the laboratory failed to establish a system to identify and assess patient test results that are inconsistent with previous patient results or are inconsistent with other test parameters.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control (QC) data, the laboratory's corrective action log the laboratories policies and procedures manual, and an interview with technical supervisor 1 (TS1), and technical supervisor 2 (TS2), the laboratory failed to document the corrective actions taken when the laboratory's chemistry instrument was operating outside of the established performance specifications. Findings include: 1. A review of the laboratory's chemistry QC data revealed that there were multiple instances of the laboratory's chemistry instrument failing QC testing initially, but passing after rerunning the failed analyte. 2. A review of the laboratory's corrective action log revealed the laboratory failed to document any corrective actions taken for days when the chemistry QC failed initially, but passed upon rerunning the analyte. 3. A review of the laboratory's policies and procedures manual revealed the laboratory is required to document the corrective action steps taken to correct the failed QC results. 4. An interview with TS1, and TS2, on June 17, 2025 at approximately 3:00 PM confirmed that the laboratory failed to document, and follow its policies and procedures to document the corrective action steps taken to correct the failed QC analytes on the laboratory's chemistry instrument.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; general supervisor, was not met. The laboratory failed to employ a general supervisor who is qualified (see D6143).
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding

	any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g). This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel files, an interview with the general supervisor (GS), and an interview with technical supervisor 1 (TS1), the laboratory failed to ensure the general supervisor was qualified. Findings include: 1. A review of the laboratory's personnel files revealed the GS had a Bachelor of Science degree in Biochemistry, but did not have two years of experience performing high complexity testing. 2. An interview with the GS, on June 17, 2025, at approximately 10:00 AM, confirmed that they had no experience in a high complexity laboratory, and the only testing experience the GS had been from an international hospital laboratory. 3. An interview with TS1, on June 17, 2025, at approximately 9:50 AM, confirmed the laboratory had failed to verify the GS had 2 years of experience with high complexity testing.