Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2241230	07/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Peak 8 Genomics	10800 E Bethany Dr, #301, Aurora, 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
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: Based on a review of the procedure manual and an interview with the laboratory director, the laboratory failed to include all test procedure requirements for the hematology complete blood count system, Quantiferon tuberculosis (QFT), and Sysmex 600 coagulation tests since March 2023. Findings Include: 1. A review of the laboratory's procedure manual for hematology, coagulation, and QFT assays revealed the procedures failed to provide step-by-step instructions for test performance, calibration and calibration verification requirements, reportable ranges and critical value ranges, limitations of the test, quality control requirements, criteria to determine

	acceptable control results and patient results, corrective actions for when there are problems with the test system, reporting patient results, and down-time procedures when the systems are inoperable. The laboratory performed approximately 40 patient tests since March 2023. 2. An interview with the laboratory directory on 07/11/2023, at approximately 11:00 AM, confirmed that the laboratory failed to have complete procedures for the laboratory test systems.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of the laboratory procedure manual, analyzer log sheets, and an interview with the laboratory supervisor, the laboratory failed to document and ensure that the hematology and coagulation analyzers maintenance activities were documented since March 2023. Findings: 1. A review of the laboratory maintenance worksheets revealed that the laboratory failed to record the maintenance activities as stated by the manufacturer for the Emerald hematology analyzer and the Sysmex coagulation analyzer since January 2023. 2. An interview with the laboratory supervisor on 7/11/2023, at approximately 11:20 AM, confirmed that the laboratory failed to document maintenance activities on the analyzers.
D5805	TEST REPORT CFR(s): 493.1291(c) 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 patient test reports and laboratory records, and an interview with the laboratory supervisor, the laboratory failed to provide normal ranges for complete blood counts (CBC), prothrombin time (PT), and Quantiferon tuberculosis (QFT) results since March 2023. Findings: 1. A review of three patient test reports and laboratory documents revealed the patient test reports failed to state normal ranges for CBC, PT, and QFT results since March 2023. The laboratory performed approximately 40 patient specimens since March 2023. 2. An interview with the laboratory supervisor on 7/11/2023, at approximately 11:30 AM, confirmed that the laboratory failed to have normal ranges stated for the tests on patient test reports.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory director, the laboratory director failed to ensure that the laboratory had a quality assessment program that identified errors in all phases of the laboratory processes to ensure reliable and accurate test performance and resulting was being performed since March 2023. Findings include: 1. The laboratory procedure manual failed to include quality assessment activities for proficiency testing, personnel, test performance, instrument maintenance and function checks, and test reporting since March 2023. 2. An interview with the laboratory director on 7/11/2023, at approximately 11:20 AM, confirmed the laboratory failed to include quality assessment activities for all phases of laboratory test performance.