Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2101156	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Summit Medical Group	140 Park Avenue, Florham Park, NJ	

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
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) Work Records (WR), Electronic Medical Record (EMR) and interview with the General Supervisor (GS) the laboratory failed to ensure test results were reported accurately for Direct Wet Mount Preparation and Potassium Hydroxide testing into the EMR on 7/22/2022 and 6/26/22. The finding includes: 1. A review of eight EMR entries revealed two patient had results as follows: a) Whit Blood Cell (WBC) positive but the EMR had no result for WBC on 7/22/22 and 6/26/22. 2. The GS confirmed on 4/24/24 at 11:30 am that the laboratory did not ensure test results were accurately recorded in the EMR.
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 surveyor review of the Final Report (FR) and interview with the General Supervisor (GS) the laboratory failed to ensure that the FR included all the required information on the date of survey. The finding include: 1. A review of two FR revealed that the Specimen collection date was not recorded in the applicable field on the FR 2. The GS confirmed on 4/24/24 at 10:45 am that FR did not have all the required information.
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: Based on surveyor review of the Test Reports (TR) for Direct Wet Mount Preparation and Potassium Hydroxide testing and interview with the General Supervisor (GS), the laboratory failed to have a Reference Interval (RI) on TR from 8/28/2015 to the date of survey. The findings include: 1. 2 out of 2 TR did not have a RI. 2. The The GS confirmed on 4/24/24 at 2:00 pm the laboratory failed to include a RI for Wet Mount Preparation and Potassium Hydroxide testing