

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2098391	(X3) Date Survey Completed 04/17/2024
Name of Provider or Supplier Summit Medical Group DbA Summit Health	Street Address, City, State 75 E Northfield Road, Livingston, 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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure that PS procedures performed for Endocrinology, Chemistry testing performed on the Cobas Integra analyzer were adequate from February 2023 to the date of survey. The findings include: 1. There was no documented evidence that a accuracy was performed for Alanine Transaminase (ALT) and Lipase. 2. The GS confirmed on 4/17/24/24 at 11:15 am that PS records were not adequate.</p>