

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2082167	<b>(X3) Date Survey Completed</b> 03/20/2024
<b>Name of Provider or Supplier</b> Summit Medical Group DbA Summit Health	<b>Street Address, City, State</b> 574 Springfield Avenue, Westfield, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Records (MR) for the Sysmex XS 1000 analyzer, Sysmex XS 1000 User Manual and interview with the General Supervisor (GS), the laboratory failed to perform and document monthly maintenance as specified by the manufacturer for the Sysmex XS 1000 used for Hematology tests in January, March and September of calendar year 2023. The findings include: 1. The User Manual states the monthly rinse sequence is to be performed monthly or every 1200 cycles. 2. There was no documented evidence monthly maintenance was performed in the months of January 2023, March 2023 and September 2023. 3. The GS confirmed on 3/19/24 at 12:15 pm there was no documented evidence monthly maintenance was performed and documented for the Sysmex XS 1000 in the above mentioned timeframe.</p>
<b>D6013</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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>

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 for Chemistry tests performed on the Cobas analyzer were adequate from March 2022 to the date of survey. The findings include: 1. There were no raw data reports for the dilution study performed on the Cobas analyzer. 2. The GS confirmed on 3/20/24 at 11:00am, the PS were not adequate.