

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2195280	(X3) Date Survey Completed 10/04/2022
Name of Provider or Supplier Lifehope Labs	Street Address, City, State 3333 Old Milton Parkway, Suite 290, Alpharetta, GA	
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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 04, 2022. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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 the laboratory tour and staff interview, the laboratory failed to have professional maintenance on the Microscope as required. Findings include: 1. Observation during the laboratory tour revealed that the Accu-Scope Microscope from Infinity 1 Lumenera was NOT calibrated annually as required. The last calibration was performed on 08/17/2017. 2. An interview with testing personnel #2 (CMS 209) and Lab director on 10/04/2022 in the laboratory at approximately 10:15 AM, confirmed the lack of the aforementioned professional maintenance on the main Microscope.</p>