

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>11D2189295</p>	<p><b>(X3) Date Survey Completed</b></p> <p>02/07/2024</p>
<p><b>Name of Provider or Supplier</b></p> <p>Viral Solutions, Llc</p>	<p><b>Street Address, City, State</b></p> <p>2900 Chamblee Tucker Road, Building #3, Atlanta, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D0000</b></p>	<p>On March 20, 2024 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations. An onsite survey was completed on February 7, 2024, to investigate complaint number GA00241728. The allegation of the General Lab Systems was substantiated; the allegation of Post Analytic Diagnostic Discrepancy was unsubstantiated. The following deficiencies were cited:</p>
<p><b>D5429</b></p>	<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 lab tour, maintenance documents review and staff interviews, the laboratory failed to perform annual calibrations for its pipettes and laboratory fume hoods as required in 2023. Findings: Based on the review of maintenance and equipment calibration records on the day of survey 2/7/2024, the following were discovered: 1.) Integra Voyager 50ul Pipettes: Serial #07034108 (Cal expired 11/23/2023), #07034658 (Expired 9/16/2023), #07039882 and #07039873 (Expired 12/12/2023), #07048940 (1250 ul Expired 12/12/2023) and #07048939 (1250 ul Expired 7/21 /2024). 2.) VS3 Quant Studio7 Flex #278874948 and VS4 Quant Studio 7 Flex #278874941 both had calibration dates Expred 01/14/2023 respectively. VS1 and VS2 Quant Studio 5 Serial #272532527 and #272533022 both calibrations Expired 11/16 /2023. 3.) Air Clean PCR 600 work station hoods #s 1, 2, 3, 4 and 5 had NO evidence of maintenance in 2022 or 2023. 4.) Interviews with the lab director and (TS) (TP#3 CMS 209) in the review room on 02/07/2024 at approximately 2:00 PM confirmed the above findings.</p>

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and interviews with the lab director (LD) and general supervisor (GS), the technical supervisor (TS) failed to perform initial training and competency on all testing personnel. Findings: 1. Review of 3 of 3 TP training and competency documents reveals the TC failed to ensure proper training and competency was performed for all TP. 2. Documents revealed: TP 1 had documented training but no semi-annual or annual competency evaluations. TP 2 and TP 3 did not have documented training, semi-annual, or annual competency evaluations. 3. Interviews with the LD and GS in the review office on 2/7/24 at 1:30 PM, confirmed the aforementioned findings.