Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2040138	03/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Unique Laboratory Solutions	8560 N Silvery Lane Suite 300, Dearborn Heights, MI	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on a record review and interview with the General Supervisor, the laboratory failed to verify performance specifications for the SalivaDirect SARS-CoV-2 RT-PCR Assay for 15 (November 2020 to February 2022) of 15 months since the laboratory started using the test system. Findings include: 1. The surveyor requested the laboratory's verification of performance specifications for the SalivaDirect SARS-CoV-2 RT-PCR Assay on 2/28/22 at 11:09 am and it was not made available. 2. An interview on 2/28/22 at 11:06 am with the General Supervisor confirmed the laboratory did not have documentation of the establishment of performance specifications for SalivaDirect SARS-CoV-2 RT-PCR Assay.