Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1038543	03/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sapphiros Laboratories, Llc	27 Drydock Ave 3r, Boston, MA	

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	A CLIA recertification survey was conducted for the Orig3n, Inc laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Technical Supervisor (TS) on 3/23/21, the laboratory failed to document and maintain a copy of all PT records as evidenced by the following: The surveyors reviewed College of American Pathologists (CAP) PT records for calendar years 2019 and 2020 on 3/23 /21. The review revealed that attestation statements provided by the PT program were not signed by analyst for the following events: 1. APOE-B 2019 Event 2 2. APOE-B 2020 Event 2 3. MGL1-B 2020 Event 2 The TS confirmed in an interview on 3/23/21 at 11:25 AM that not all attestation statements were signed by the analyst. .
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS) and Laboratory Director (LD) on 3/23/2021, the laboratory failed to indicate the name and address of the laboratory where the test was performed on the final test report as evidenced by the following: Surveyors reviewed eleven (11) laboratory final reports for testing performed between 4/10/19 and 3/5/21 on 3/23/21. The review revealed that the name and address of the laboratory where testing was performed was not present on three (3) out of (11) reports reviewed. 1. The laboratory performed 23,614 COVID-19 tests between March 2020 when the test was implemented through August 2020. Final reports during this time period did not indicate the address of the laboratory where testing was performed. 2. a) The laboratory utilized Clinical Research Sequencing Platform as a reference laboratory. Final reports from August 2020 through December 2020 did not include the full name of the laboratory where testing was performed. The final report indicates "Broad Institute CRSP Laboratory." The name of the laboratory is Clinical Research Sequencing Platform. b) 18,959 COVID-19 specimens were sent to the reference laboratory and were reported without the full name of the laboratory where testing was performed. 3. The TS and LD confirmed in an interview on 3/23/2021 at 5:45 PM that final test reports did not all contain the full name and address of the laboratory where the test was performed. This is a repeat deficiency from a complaint survey performed on 1/31/2018. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical supervisor (TS) on 3/23/21, the TS failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: 1. Surveyors reviewed the CMS 209 Laboratory Personnel Report on 3/23/21. The review revealed that there were three (3) new testing persons (TP) hired since the last CLIA recertification survey on 10/11 /17. 2. Surveyors reviewed personnel competency assessments on 3/23/21. The review revealed that there was no documentation of semiannual competency evaluations for TP1 who had been working for over a year. 3. The TS confirmed in an interview on 3 /23/21 at 10:50 AM that no semiannual competency evaluations had been performed on TP1.