Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1038543	08/26/2020
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	An onsite complaint investigation of the Orig3n, Inc laboratory was performed on 8/7 /2020 and 8/21/2020. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: This Condition is not met as evidenced by: Based on surveyor record review and staff interviews, the laboratory failed to document the daily sanitizing of the laboratory benches and equipment utilized for the COVID-19 test (refer to D5433); failed to ensure control materials included one that is capable of detecting errors in the extraction phase of testing (refer to D5453); failed to establish a quality control monitoring system capable of identifying contamination during the extraction phase of testing and failed to follow quality assessment policies and procedures for COVID-19 positivity rates (refer to D5791); and failed to maintain a suitable copy of corrected reports when errors in the reported patient test results were detected (refer to D5821).
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result

	reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document daily sanitizing of the laboratory benches and equipment. This Standard is not met as evidenced by: 1. On 8/7/2020 surveyors reviewed standard operating procedure (SOP) SOP CV2020.02.MA COVID-19 RNA Extraction and Purification - Omega Bio-Tek Protocol, Section 5.1.1.2 and SOP 300.004 Safety Manual, Section 7.6. Each SOP stated that the laboratory benches and equipment were to be sanitized daily with 70% v /v Ethanol. The review revealed that the laboratory failed to document the daily sanitizing of the laboratory benches and equipment from 4/27/2020 to 8/6/2020. 2. The laboratory director confirmed in an interview on 8/7/2020 at 2:55 P.M. that the laboratory performed daily sanitization of the laboratory benches and equipment but failed to maintain written documentation.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure control materials included one that is capable of detecting errors in the extraction process. This Standard is not met as evidenced by: 1. On 8/21/2020 surveyors reviewed COVID-19 quality control (QC) records from calendar months April, May, June, July, and August 2020, Standard Operating Procedure (SOP) titled SOP.CV2020.02.MA COVID-19 RNA Extraction and Purification - Omega Bio-Tek Protocol, COVID-19, Master Count Tracking logs from April 27, 2020 to August 5, 2020, the laboratory's spreadsheet of positive COVID-19 counts per state and institution from 7/30/2020 to 8 /2/2020, and the laboratory's spreadsheet of all positive COVID-19 results from 7/30 /2020 to 8/2/2020. 2. The review revealed that the laboratory failed to include a negative extraction control during the extraction phase of testing that is capable of detecting contamination in the extraction process. 3. The laboratory director stated on 8/21/2020 at 11:15 AM that at least two controls were included in the extraction phase but were not included in the extraction reagent pipetting step and would not detect contamination of these reagents. 4. Surveyors reviewed the laboratory's COVID-19 Master Count Tracking logs on 8/21/2020. According to the logs, 3,761 specimens were run from 7/30/2020-8/2/2020. 5. On 8/21/2020, surveyors reviewed the laboratory's spreadsheet of positive COVID-19 counts per state and institution resulted from 7/30/2020 to 8/2/2020 which indicated that 406 samples tested positive for COVID-19. 6. On 8/21/2020, surveyors reviewed the laboratory's spreadsheet of all positive COVID-19 results from 7/30/2020 to 8/2/2020 including retested results. 337 positive specimens were rerun at the laboratory and subsequently were reported as negative for COVID-19. 46 of these specimens were rerun at a reference laboratory and were reported as negative for COVID-19. 7. The laboratory reported 383 false

	positive results for COVID-19. 8. The laboratory director confirmed through interview on 8/21/2020 at 11:15 AM that the QC utilized in the extraction step was not adequate to detect contamination in the extraction process. 9. The laboratory began testing for COVID-19 4/27/2020 and reported 23,513 COVID-19 results.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and follow procedures for an ongoing mechanism to monitor and ensure reliable and accurate COVID-19 test results. This Standard is not met as evidenced by: 1. On 8/7/2020, surveyors reviewed the Standard Operating Procedure (SOP) 500.001 Quality Assurance Policies, Section 3.4 and the COVID-19 Master Count Tracking logs from April 27, 2020 to August 5, 2020. The review revealed that the laboratory tracked daily COVID-19 positivity rates but the daily positivity rates were not "objectively assessed" per Section 3.4 of the SOP. 2. The laboratory director and CEO confirmed in an interview on 8/7/2020 at 2:30 P.M. that the laboratory tracked daily COVID-19 positivity rates but failed to assess and correct any problems that arose due to higher than normal positivity rates. 3. On 8/21/2020, surveyors reviewed quality control (QC) records from calendar months April, May, June, July, and August 2020 and policy SOP.CV2020.02.MA COVID-19 RNA Extraction and Purification - Omega Bio-Tek Protocol revealed that the QC in the extraction phase was not adequate enough to detect contamination. 4. The laboratory director confirmed through interview on 8/21/2020 at 11:15 AM that the QC utilized in the extraction step was not adequate to detect contamination in the extraction process and there was no other method for detecting contamination through the entire extraction phase of testing.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain duplicate copies of the original and the corrected reports. This Standard is not met as evidenced by: 1. The surveyors reviewed two corrected reports on 8/21/2020 for false positive COVID-19 results from test dates 7/31/2020 and 8/1/2020. The review revealed that the laboratory's corrected reports failed to indicate the fact that the report is a corrected report. 2. The laboratory director and the CEO and president of the laboratory confirmed in an interview on 8/21/2020 at 10:30 AM that all the corrected

	reports issued did not indicate that they were corrected reports. The CEO stated that corrected reports were submitted to the ordering providers in folders labeled as corrected. 3. The laboratory issued 337 corrected reports for COVID-19.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: This Condition is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the sub-specialty of Virology. The LD failed to indicate the fact that the report is a corrected report on 337 corrected reports, this is a repeat deficiency (refer to D6082); failed to ensure the daily sanitizing of the laboratory benches and equipment were documented (refer to D6087); failed to ensure that the quality control programs established assure the quality of laboratory services provided and to identify failures in quality as they occur (refer to D6093); and failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (refer to 6094).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure quality laboratory services specifically the postanalytic phase of testing. This Standard is not met as evidenced by: 1. The surveyors reviewed two corrected reports for false positive COVID-19 results from test dates 7/31/2020 and 8/1/2020. The review revealed that the laboratory's corrected reports failed to indicate the fact that the report is a corrected report. 2. The LD confirmed in an interview on 8/21/2020 at 10:30 A.M. that the laboratory failed to maintain a suitable copy of corrected reports. 3. The laboratory issued 337 corrected reports for COVID-19 testing that did not indicate that the reports were corrected. (Refer to D5821) This is a repeat deficiency from a complaint investigation conducted on 1/31/2018.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on record review and confirmed through interview, the laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results. This Standard is not met as evidenced by: 1. On 8/7/2020 the surveyors reviewed standard operating procedures (SOP) SOP CV2020.02.MA COVID-19 RNA Extraction and Purification - Omega Bio-Tek Protocol, Section 5.1.1.2 and SOP 300.004 Safety Manual, Section 7.6. Each SOP stated that the laboratory benches and equipment were to be sanitized daily with 70% v /v Ethanol. The review revealed that the laboratory director failed to ensure the daily sanitizing of the laboratory benches and equipment were documented. 2. The laboratory director confirmed in an interview on 8/7/2020 at 2:55 P.M. that the laboratory performed daily sanitization of the laboratory benches and equipment but failed to maintain written documentation. (Refer to D5433)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that quality control (QC) programs assured quality laboratory services and identified failures in quality as they occurred. This Standard is not met as evidenced by: 1. The laboratory director failed to include a negative extraction control during the extraction phase of testing that is capable of detecting contamination in the extraction process. The laboratory director stated that at least two controls were included in the extraction phase but were not included in the extraction reagent pipetting step. 2. The laboratory reported 383 false positive results for COVID-19 due to contamination in the reagent set up prior to extraction. 3. The laboratory director confirmed through interview on 8 /21/2020 at 11:15 AM that the QC utilized in the extraction step was not adequate enough to detect contamination in the extraction process. (Refer to D5453)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) did not ensure that quality assessment programs assured the quality of laboratory services or identified failures in quality. This Standard is not met as evidenced by: 1. On 8/7/2020, surveyors reviewed the Standard Operating Procedure (SOP) 500.001 Quality Assurance Policies, Section 3.4 and the COVID-19 Master Count Tracking logs from April 27, 2020 to August 5, 2020. The review revealed that the laboratory tracked daily COVID-19 positivity rates but the daily positivity rates were not "objectively

	assessed" per Section 3.4 of the SOP. 2. The LD and CEO confirmed in an interview on 8/7/2020 at 2:30 P.M. that the laboratory tracked daily COVID-19 positivity rates but failed to assess and correct any problems that arose due to higher than normal positivity rates. 3. On 8/21/2020, surveyors reviewed of quality control (QC) records from calendar months April, May, June, July, and August 2020 and policy SOP. CV2020.02.MA COVID-19 RNA Extraction and Purification - Omega Bio-Tek Protocol revealed that the QC in the extraction phase was not adequate to detect contamination. 4. The laboratory director confirmed through interview on 8/21/2020 at 11:15 AM that the QC utilized in the extraction step was not adequate to detect contamination in the extraction process and there was no other method for detecting contamination through the entire extraction phase of testing. (Refer to D5791)