

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1038543	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Sapphiros Laboratories, Llc	Street Address, City, State 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 complaint investigation of the Orig3n, Inc. laboratory was performed on 1/31/18. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide documentation of a written or electronic request for patient testing from an authorized person as evidenced by the following: a) Record review was conducted on 1/31/18 of five (5) genetic final test reports (customer IDs: f2121b73-a4d9-4f38-9cb2-099fc7df99db, f90a8afc-7b85-40dd-8c1 4-59bdb1 e8a556, 8d7ab99e-f83b-45ce-ba47-f4cf582bf573, 9laf7e9-5353-4260-81ci-ccf0b5d066ic, and 6817d9b5-102c-42c7-a564-b7f3747b67ec). b) During the survey, the surveyor requested proof that the tests ordered were from an authorized person. c) The chief operating officer interviewed on 1/31/18 at 12:41 PM indicated that the data to review was in a database and there was no means of obtaining the data during the time of the survey to review and confirm that the requests for testing came from an authorized person. Also refer to D8103. .</p>
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable,</p>

a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to solicit the date of collection on the test requisition. a) Record review conducted on 01/31/18 of a blank patient test request form revealed that the date of specimen collection was not on the test requisition. b) Interview with the with the laboratory technical supervisor on 1/31/18 at 9:42 AM confirmed this finding.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on record review and staff interview conducted on 01/31/2018, the laboratory failed to have a system in place to ensure that test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner as evidenced by the following: a) During the time of the survey, laboratory personnel were requested to show all patient-specific data that led up to the final report of five (5) patient specimens tested (customer IDs: f2121b73-a4d9-4f38-9cb2-099fc7df99db, f90a8afc-7b85-40dd-8c1 4-59bdb1 e8a556, 8d7ab99e-f83b-45ce-ba47-f4cf582bf573, 9laf7e9-5353-4260-81ci-ccf0b5d066ic, and 6817d9b5-102c-42c7-a564-b7f3747b67ec). b) Interview with laboratory personnel on 01/31/2018 at 12:30 PM revealed that they were unable to provide and demonstrate that patient-specific data was being transmitted electronically in an accurate and reliable manner and that the final report included all of the necessary required information for reporting c) Interview with the technical supervisor on 1/31/18 at 12:41 PM confirmed that neither she nor the laboratory director had access to the post analytic portion of the reporting system to ensure compliance with the regulatory requirements for the test report and that all necessary information regarding test results were accurate.

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 staff interview, the laboratory failed to ensure that the final report contained all required information for interpretation as evidenced by the following: a) Record review conducted on 01/31/2017 of five (5) final patient genetic test reports (customer IDs: f2121b73-a4d9-4f38-9cb2-099fc7df99db, f90a8afc-7b85-40dd-8c1 4-59bdb1 e8a556, 8d7ab99e-f83b-45ce-ba47-f4cf582bf573, 9laf7e9-5353-4260-81ci-ccf0b5d066ic, and 6817d9b5-102c-42c7-a564-b7f3747b67ec) revealed that five (5) of five (5) of the final reports did not include the following: 1. A second unique patient identifier or identification number; 2. The address of the laboratory location where the test was performed; and, 3) The test report date. b) The laboratory technical supervisor confirmed in an interview on 1/31/18 at 11:10 AM that the final report did not include the above information. .

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 observation and record review, the laboratory director failed to ensure that the testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, specifically the postanalytic phase of testing as evidenced by the following: a) During the time of the survey laboratory personnel were requested to show all patient-specific data that led up to the final test report for five (5) patient specimens tested (customer IDs: f2121b73-a4d9-4f38-9cb2-099fc7df99db, f90a8afc-7b85-40dd-8c1 4-59bdb1 e8a556, 8d7ab99e-f83b-45ce-ba47-f4cf582bf573, 9laf7e9-5353-4260-81ci-ccf0b5d066ic, and 6817d9b5-102c-42c7-a564-b7f3747b67ec). b) Observation of laboratory personnel revealed that they were unable to provide patient-specific data to demonstrate that test results were being transmitted electronically in an accurate and reliable manner and that the final report included all of the necessary required information for reporting (refer to D5801 and D5805). c) The technical supervisor interviewed on 1/31/18 at 12:41 PM confirmed that neither she nor the laboratory director had access to the post analytic portion of the reporting system in order to ensure compliance with the regulatory requirements for the test report and ensure that all necessary information regarding test results were accurate.

D8103

BASIC INSPECTION REQUIREMENTS

CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. The laboratory did not provide, upon request, all information and data needed by the CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part as evidenced by the following: a) Record review was conducted on 01/31/18 of five (5) genetic testing final test reports (customer IDs: f2121b73-a4d9-4f38-9cb2-099fc7df99db, f90a8afc-7b85-40dd-8c1 4-59bdb1 e8a556, 8d7ab99e-f83b-45ce-ba47-f4cf582bf573, 9laf7e9-5353-4260-81ci-ccf0b5d066ic, and 6817d9b5-102c-42c7-a564-b7f3747b67ec). b) At the time of the survey, a request was made by the surveyor to provide all patient-specific data that led up to the final reports. The data was not able to be provided to the surveyor for review during the time of the survey. c) The chief operating officer stated in an interview on 1/31/18 at 12:41 PM that the data was stored in a database off site and was not retrievable in order to be reviewed during the time of the survey.