

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2212590	<b>(X3) Date Survey Completed</b>  11/05/2021
<b>Name of Provider or Supplier</b>  Ocean Biosciences Llc	<b>Street Address, City, State</b>  45 Ne 26th Street, Miami, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial certification survey conducted on 10/21/2021-11/05/2021, found the Ocean Biosciences LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified of the Immediate Jeopardy on 11/01/2021 at 11:10 AM. The laboratory failed to validate their method of spraying bleach and then wiping with alcohol on COVID-19 nasal collection tubes that leaked or spilled in the bag for viability from 06/23/2021 to 10/25/2021 Polymerase chain reaction (PCR) testing. The laboratory failed to perform a stability study on nasal specimens for transportation at room temperature and storage for 2-8 Celsius (C) used in COVID-19 PCR testing from 06/23/2021 to 10/25/2021. The laboratory failed to perform a stability study on Saliva collection tubes stored in refrigerator for retesting of COVID-19 PCR up to 7 days from 06/23/2021 to 10/25/2021 (See D5311). The laboratory failed to store TaqPath COVID-19 Positive controls at -70 Celsius(C) as instructed by the manufacturer from 06/23/2021 to 10/25/2021 (see D5413). The laboratory failed to complete a validation for storing elution plates in fluctuating temperatures from -80 C to -70 C that contained extracted Ribonucleic acid (RNA), interfering substances, and unvalidated nasal and saliva collection tubes performing COVID-19 PCR testing with the out of Emergency Use Authoritaization TaqPath Combo Kit before patient testing from 06/23/2021 to 10/25/2021 (see D5423). The laboratory failed to establish and validate the method for using positive controls outside of manufacturer guidelines before patient testing starting on 06/23/2021 with the unvalidated TaqPath COVID-19 Combo Kit. (see D5425) The following Conditions were not met: D5300-Preanalytic Systems D5400-Analytic Systems D6076-Laboratory Director D6141-General Supervisor D6168-Testing Personnel
<b>D5300</b>	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides</p>

equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to validate their method of spraying bleach and then wiping with alcohol on COVID-19 nasal collection tubes that leaked or spilled in the bag for viability from 06/23/2021 to 10/25/2021 Polymerase chain reaction (PCR) testing. The laboratory failed to perform a stability study on nasal specimens for transportation at room temperature and storage for 2-8 Celsius (C) used in COVID-19 PCR testing from 06/23/2021 to 10/25/2021. The laboratory failed to perform a stability study on Saliva collection tubes stored in refrigerator for retesting of COVID-19 PCR up to 7 days from 06/23/2021 to 10/25/2021. (See D5311)

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to validate their method of spraying bleach and then wiping with alcohol on COVID-19 nasal collection tubes that leaked or spilled in the bag to for viability before Polymerase chain reaction (PCR) testing from 06/23/2021 to 10/25/2021. The laboratory failed to perform a stability study on nasal specimens for transportation at room temperature and storage for 2-8 Celsius (C) used in COVID-19 PCR testing from 06/23/2021 to 10/25/2021. The laboratory failed to perform a stability study on Saliva collection tubes stored in refrigerator for retesting of COVID-19 PCR up to 7 days from 06/23/2021 to 10/25/2021. Findings included: During an observation of the accessioning area on 10/22/2021 at 11:22 AM revealed COVID-19 specimen collection tubes that had leaked in biohazard bags during transit were placed under the BSCII Hood. An accessioning technician removed a COVID-19 specimen collection tube from one of the bags. The tube was placed on a paper towel. The accessioning technician sprayed the tube with bleach and wiped with a paper towel covered in alcohol. This process was repeated with the other tubes. Review of Cleaning Procedure revealed there was no written cleaning procedure with bleach and alcohol for COVID-19 specimen collection tubes that had leaked. There was no written validation for this method to ensure COVID-19 specimens were not affected. An observation of COVID-19 specimen receiving area on 10/22/2021 at 10:51 AM revealed COVID-19 specimen collection tubes were received in the laboratory by courier boxes with no ice or temperature gauges. Review of the Sorfa Disposables Sample Collection Kit states "the transport medium has not been reviewed by the Food and Drug Administration (FDA). Optimum storage temperature of collection tubes are 5C to 25C." During an observation of the Molecular Testing Room on 10/22/2021 at 12:00 PM revealed K2-Scientific FH-04-002 refrigerator was used to store COVID-19 Nasal and Saliva collection specimen

for first time testing and retesting in PCR up to 7days. Review of K2-Scientific FH-04-002 Daily Recording log revealed temperature recordings of 1C to 7C for COVID-19 specimen storage from 06/23/2021 to 10/25/2021. Review of Taqpath COVID-19 Combo Kit procedure stated "Taqpath Combo Kit are only for use under the Food and Drug Administration's Emergency Use Authorization. Patient samples must be collected according to appropriate laboratory guidelines. Positive and negative test controls must be included to accurately interpret patient test results. Store patient samples according to CDC guidelines." Review of CDC guidelines states "Store respiratory specimens at 2-8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below. Store extracted nucleic acid samples at -70C or lower." Review of Stability Study for COVID-19 Specimen collection tubes revealed the was no written documentation of a stability study for Sorfa Disposables samples collection kit used for nasal collection and SDNA-1000 Spectrum DNA innovation Devices are used for saliva collection to be stored at 2C-8C for 7days in refrigerator or transportation . During an interview on 10/27/2021 at 1:00 PM, the Operations Manager stated 22,217 patients were tested by the unvalidated Taqpath COVID-19 Combo Kit from 06/23/2021 to10/25/2021. During an interview on 11/02/2021 at 10:15 AM, the Operations Manager, Technical Supervisor (TS) A and TS B confirmed the failure to validate the method of spraying bleach and alcohol on nasal collection tubes and perform a stability study on saliva collection and nasal collection kits.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on observation, record review and interview, the laboratory failed to store TaqPath COVID-19 Positive controls at -70 Celsius(C) as instructed by the manufacturer from 06/23/2021 to 10/25/2021. (see D5413) Based on observation, record review and interview, the laboratory failed to complete a validation for storing elution plates in fluctuating temperatures from -80 Celsius (C) to -70 C that contained extracted Ribonucleic acid (RNA), interfering substances, and unvaildated nasal and saliva collection tubes for performing COVID-19 PCR testing with the out of Emergency Use Authoritaization TaqPath Combo Kit before patient testing from 06/23/2021 to 10/25/2021. (see D5423) Based on observation, record review and interview, the laboratory failed to establish and validate the method for using positive controls outside of manufacturer guidelines before starting patient testing on 06/23/2021 with the unvalidated TaqPath COVID-19 Combo Kit. (see D5425)

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to store TaqPath COVID-19 Positive controls at -70 Celsius(C) as instructed by the manufacturer from 06/23/2021 to 10/25/2021. Findings Included: Review of Applied Biosystems TaqPath COVID-19 Positive Control package stated "store positive control at -70 C." During an observation of the Molecular Testing Room on 10/21/2021 at 1:30 PM revealed the Extraction K2 Scientific Freezer FH80-001(Extraction Freezer) held TaqPath COVID-19 Positive Control boxes and elution plates. Review of Extraction FH80-001 Freezer Daily log displayed temperatures of above -70 C for 5 out of 130 days from 06/23/2021 to 10/25/2021 for the Extraction freezer. For 125 out 130 days temperatures were record below -70 C from 06/23/2021 to 10/25/2021 for the extraction freezer. During an interview on 11/02/2021 at 10:00 AM, the Operations Manager, Technical Supervisor (TS) A and TS B confirmed the TaqPath COVID-19 Positive Controls were not stored at -70 C.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to complete a validation for storing elution plates in fluctuating temperatures from -80 Celsius (C) to -70 C that contained extracted Ribonucleic acid (RNA), interfering substances, and unvalidated nasal and saliva collection tubes for performing COVID-19 PCR testing with the out of Emergency Use Authoritaization TaqPath Combo Kit before patient testing from 06/23/2021 to 10/25/2021. Findings included: Review of Taqpath COVID-19 Combo Kit FAQs stated "The TaqPath COVID-19 Combo kit is currently approved for use with viral RNA extracted from these six specimen types: bronchoalveolar lavage (BAL), mid-turbinate swabs, nasal swabs, nasopharyngeal swabs, nasopharyngeal aspirate (nasal aspirate), and oropharyngeal swabs. Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences. We did not validate any specific transport and storage solution; your lab is responsible for choosing and verifying the transport media you have selected and complying with manufacturer guidance for the storage media and vial you intend to use. Any changes to the protocol are considered

off-label use and invalidate compliance with the IFU." During an observation of Molecular Testing Room on 10/21/2021 at 1:30 PM revealed the Extraction K2 Scientific Freezer FH80-001(Extraction Freezer) held TaqPath COVID--19 Positive Control boxes and elution plates. Review of Extraction FH80-001 Freezer Daily Log displayed temperatures of above -70 C for 5 out of 130 days from 06/23/2021 to 10/25/2021 for the Extraction freezer. For 125 out 130 days temperatures were record below -70 C from 06/23/2021 to 10/25/2021 for the extraction freezer. Review of Nasal and Saliva Taqpath COVID-19 Combo Kit validations revealed no documentation of interfering substances done for the validation since 05/11/2021. Validation procedure stated that elution plates are stored at -80 C with extraction materials. Based on observation, record review and interview, the laboratory failed to validate their method of spraying bleach and then wiping with alcohol on COVID-19 nasal collection tubes that leaked or spilled in bag to for viability before Polymerase chain reaction (PCR) testing from 06/23/2021 to 10/25/2021. The laboratory failed to perform a stability study on nasal specimens for transportation at room temperature and storage for 2-8 Celsius (C) used in COVID-19 PCR testing from 06/23/2021 to 10/25/2021. The laboratory failed to perform a stability study on Saliva collection tubes stored in refrigerator for retesting of COVID-19 PCR up to 7 days from 06/23/2021 to 10/25/2021.(See 5311) During an interview with Operations Manager on 10/25/2021 at 12:00 PM, She stated that 22,217 patients were tested with unvalidated TaqPath COVID-19 Combo Kit from 06/23/2021 to 10/25/2021. During an interview on 11/02/2021 at 10:00AM, the Operations Manager, Technical Supervisor(TS) A and TS B confirmed failure to complete a validation for outside manufacturer guidelines usage of TaqPath COVID-19 Combo Kit for testing with specimen collection tubes with no stability study, storing elution plates below -80 C and missing interfering substances before patient testing.

**D5425**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(3)

The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to establish and validate the method for using positive controls outside of manufacturer guidelines before starting patient testing on 06/23/2021 with the unvalidated TaqPath COVID-19 Combo Kit. Findings included: Based on observation, record review and interview, the laboratory failed to store TaqPath COVID-19 Positive controls at -70 Celsius(C) as instructed by the manufacturer from 06/23/2021 to 10/25/2021. (See D5413) Review of Taqpath COVID-19 Combo Kit stated "TaqPath COVID 19 Control, not diluted (1 104 copies/L) is stored at 3.6-4.6C for 48 hours. TaqPath COVID 19 Control working concentration (25 copies/L) is stored at 3.6-4.6C (including in open tubes) for 48 hours." An observation of the Molecular Testing Room on 10/22/2021 at 12:00 PM revealed the K2-Scientific FH-20-0001 freezer was storing TaqPath COVID 19 Positive Control working concentration (the positive control with dilution buffer) from -10 to -21.5C past 48 hours for daily use. During interview with a Thermofisher technician on 10/27/2021 at 1:47 PM, the Thermofisher technician stated "upon dilution, the positive control material should be kept at 2-8C for up to 8 hours, and not subject to further freeze-thaw cycles." Review of K2-Scientific FH-20-0001 freezer revealed freezer temperature log ranges from -10 C to -21.5 C from 6/1

/2021 to 9/30/2021. Review of Nasal and Saliva TaqPath validation showed there was no documentation of validation for the positive control to be stored outside of -70 C used and then used to make diluted positive working concentrations stored in a -10 C to -20 C freezer past 48 hours for daily use. During an interview on 10/27/2021 at 1:00 PM, the Operations Manager stated 22,217 patients were tested by the unvalidated TaqPath COVID-19 Combo Kit from 06/23/2021 to 10/25/2021. During an interview on 11/02/2021 at 10:00 AM, the Operations Manager confirmed the laboratory failed to establish and validate the method for using positive controls outside of manufacturer guidelines before starting patient testing on 06/23/2021 with the unvalidated TaqPath COVID-19 Combo Kit.

**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:  
Based on record review and interview, the laboratory director failed to have 4(TP# E, TP #F, TP# G and TP# I) out of 11 testing personnel(TP) licensed by the State of Florida to perform unvalidated COVID-19 Polymerase chain reaction (PCR) testing. (See D6079) Based on record review and interview, the laboratory director failed to ensure the TaqPath COVID-19 Combo Kit along with the positive controls were validate before patient testing from 06/23/2021 to 10/25/2021. (See D6086)

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory director failed to have 4(TP#E, TP# F, TP# G and TP# I) out of 11 testing personnel(TP) licensed by the State of Florida to perform unvalidated COVID-19 Polymerase chain reaction (PCR) testing. Findings Included: Based on record review and interview, the laboratory failed to have 4(TP#E, TP# F, TP# G and TP# I) out of 11 testing personnel(TP) licensed by the State of Florida to perform unvalidated COVID-19 Polymerase chain reaction (PCR) testing. (See D6170) During an interview on 11/02/2021 at 10:06 AM, the Operations Manager confirmed the laboratory director failed to have 4 out of 11 TP licensed by the State of Florida to perform unvalidated COVID-19 PCR testing.

<p><b>D6086</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview, the laboratory director failed to ensure the TaqPath COVID-19 Combo Kit along with the positive controls were validated before patient testing from 06/23/2021 to 10/25/2021. Findings included: Based on observation, record review and interview, the laboratory failed to complete a validation storing elution plates in fluctuating temperatures from -80 Celsius (C) to -70 C that contained extracted Ribonucleic acid (RNA) , interfering substances, and unvalidated nasal and saliva collection tubes for performing COVID-19 PCR testing with the out of Emergency Use Authoritaization TaqPath Combo Kit before patient testing from 06/23/2021 to 10/25/2021. (See D5423) Based on observation, record review and interview, the laboratory failed to establish and validate the method for using positive controls outside of manufacturer guidelines before starting patient testing on 06/23/2021 with the unvalidated TaqPath COVID-19 Combo Kit. (See D5425) During an interview on 11/02/2021 at 10:07 AM, the Operations Manager confirmed the laboratory director failed to ensure the TaqPath COVID-19 Combo Kit along with the positive controls were validate before patient testing from 06/23/2021 to 10/25/2021.</p>
<p><b>D6141</b></p>	<p><b>GENERAL SUPERVISOR</b>  CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p> <p>This CONDITION is not met as evidenced by:  Based on record review and interview, the general supervisor (GS) failed to sign COVID-19 temperature logs, COVID-19 extraction room maintenance logs and GS duties documents instead of the operations manager from 06/01/2021 to 09/30/2021. (See D6144)</p>
<p><b>D6144</b></p>	<p><b>GENERAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview, the General Supervisor (GS) failed to sign COVID-19 temperature logs, COVID-19 extraction room maintenance logs and GS duties documents instead of the Operations Manager from 06/01/2021 to 9/30/2021. Findings included: Review of CMS-209 Laboratory Personnel Report showed GS listed as the GS. Review of Employee records revealed Operations Manager (OM)</p>

with an associate degree in Health Administration and BS in Health Management. OM has no license from the State of Florida in Medical Technology. Review of Molecular Temperature logs shows OM signing and reviewing temperature logs from 06/1/2021 to 09/30/2021 with no GS a signature. Review of COVID-19 Extraction maintenance logs shows OM signing and reviewing temperature logs from 06/1/2021 to 09/30/2021 with no GS a signature. Review of General Supervisor Duties Sheet revealed a signatures by OM performing GS duties and no signature by GS A from 07/24/2021 to 09/24/2021. During an interview on 11/02/2021 at 10:05 AM, the OM confirmed she was signing on GS signature required documents.

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on record review and interview, the laboratory failed to have 4(TP# E,TP# F, TP# G and TP# I) out of 11 testing personnel(TP) licensed by the State of Florida to perform unvalidated COVID-19 Polymerase Chain Reaction (PCR) testing. (See D6170)

**D6170**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to have 4(TP# E,TP# F, TP# G and TP# I) out of 11 testing personnel(TP) licensed by the State of Florida as a Medical Technologist to perform unvalidated COVID-19 Polymerase chain reaction (PCR) testing. Findings included: Review of CMS-209 Laboratory Personnel Report showed TP# E, TP# F, TP# G and TP# I were TP. Review of Employee records exhibited TP# E has a Bachelor of Arts in Chemistry from Florida International University and no state of Florida license for Medical Technologist. TP# E was hired on 03/22/2021. TP# F has a Bachelor of Sciences from Florida International University, Public Health Technician license and no State of Florida Medical Technologist license to perform testing in an independent laboratory. TP# F was hired on 09/17/2021. TP# G has a Bachelor degree in Psychology with a minor in Chemistry, Public Health Technician license and no State of Florida Medical Technologist license to perform testing in an independent laboratory. TP# G was hired on 10/11/2021. TP# I has a Bachelor of Science in Chemistry from Florida International University and no State of Florida license for Medical Technologist. TP# I was hired on 09/26/2021. Review of Competency assessment records revealed TP# E was hired and has been performing COVID-19 PCR testing since 09/03/2021. TP#F has been performing COVID-19 molecular testing since 09/23/2021. TP# G has been performing COVID-19 molecular testing since 10/15/2021. TP# I has been performing COVID-19 molecular testing since 10/5/2021. During an interview on 11/02/2021 at 10:15 AM, the Operations Manager, Technical Supervisor (TS) A and TS B

confirmed 4 out of 11 TP did not have a State of Florida Medical Technologist license to perform COVID-19 PCR testing.