Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2212590	07/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ocean Biosciences Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted from 06/29/2023 to 07/07/2023 found that the OCEAN BIOSCIENCES LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were cited: -D5300 Preanalytic Systems -D6076 Laboratory Director -D6141 General Supervisor
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 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 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 monitor and define the transport temperature of specimens delivered to the laboratory for TaqPath COVID-19 and COVID FLU AB TaqPath testing. Refer to 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 monitor and define the transport temperature of specimens delivered to the lab for TaqPath COVID-19 PCR and COVID Flu AB TaqPath testing. Findings included: On 06/29 /2023 at 09:30 AM, there was no temperature gauge to monitor specimens arriving in the lab via courier to the accessioning area for TaqPath COVID-19 and COVID Flu AB TaqPath testing. Review of "Taqpath COVID-19 Assay Protocol" signed by laboratory director (LD) on 03/28/2023 read "Validated nasal sample kits collection tubes are stable at room temperature and 2-8 Celsius (C) for 7 days." (Written as seen) There was no documentation that defined room temperature. Review of "COVID Flu AB Taqpath Validation Report-MIA" signed by laboratory director (LD) on 02/14 /2023 read "Validated nasal sample kits collection tubes are stable at room temperature and 2-8 Celsius (C) for 7 days." (Written as seen) Review of "COVID Flu AB TaqPath Validation Report Medschenker Miami "(written as seen) policy signed by LD on 03/07/2023 stated that Medschenker STM: Smart Transport Medium is used as the nasal collection tube. The Stability study section was missing a temperature that was defined for room temperature in the study. Review of Temperature logs for accessioning area revealed no documentation of temperature logs for 2022 to 2023 for specimens arriving via courier for Covid-19 PCR testing. Review of Patient Reports revealed the following: a. Patient#1 delivered from Hialeah and had no courier temperature on 11/04/2022 for COVID-19. b. Patient#2 delivered from Los Angeles and had no courier temperature on 11/30/2022 for COVID-19. c. Patient#3 delivered from Hialeah and had no courier temperature on 11/30/2022 for COVID-19. On 07/05 /2023 at 01:30 PM, Director of Research and Development and Quality Compliance stated 4,343 COVID samples were from vendors (local clinics/shipped in). On 07/07 /2023 at 11:00 AM, the lab confirmed failure to monitor and define the transport temperature of specimen delivered to the lab for COVID-19 testing.
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 ensure that the laboratory had a qualified General Supervisor. Refer to D6101.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by:

	Based on record review and staff interviews, the Laboratory Director failed to ensure that the laboratory had a qualified General Supervisor from 01/01/2022 to 06/29/2023. Findings included: -Refer to D6143.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 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. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a qualified General Supervisor. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual

	providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m). This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a General Supervisor with Supervisor Florida License from 01/01/2022 to present. Findings included: Review of FORM CMS-209 Laboratory Personnel Report dated and signed by the Laboratory Director on 06/27/2023 revealed that: a) The Laboratory Director (LD) was acting also as Clinical Consultant (CC) and Technical Supervisor (TS). b) There was one General Supervisor (GS)#A that was also Testing Personnel (TP)#A. c) There was a second TP, TP # B. -Review of "General Supervisor Job Description", reviewed by the LD on 03/08/2023 revealed the following: "The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required." -Review of personnel records for GS#A revealed that she did not have a Supervisor License for Florida. -Review of "Delegation of Duties Laboratory Director to General Supervisor" letters records revealed that the LD signed three Delegation letters in the period reviewed with the following dates: 07/13/2022, 02/13/2023 in which was listed as GS that was no longer with the laboratory (GS#B) and 04/18/2023 for GS#A. -Review of personnel records for the person listed as GS in the letters for 07/13/2022 and 02/13/2023, revealed that she did not have the Supervisor license (GS #B). During an interview on 06/29/2023 at 04:30 PM, with the laboratory manager, she confirmed that the GS#A listed in the FORM CMS-209 and GS#B listed in the Delegation of Duties letters of 07/13/2022 and 02/13/2023 did not have a Florida License as Supervisor.