Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0914874	02/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Biomedical Technologies Inc	3555 Fiscal Court Ste 9, Riviera Beach, 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	An announced CLIA recertification survey was conducted at Oxford Biomedical Technologies Inc on February 6 - 19, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6168 - Testing Personnel 493-1487
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the manufacturer's temperature requirements, quality control records, and interview, the laboratory failed to record the temperature and humidity of the preparation room from 11/08/2024 to 02/06/2025. Findings: 1. Review of the CyBi - Selma User manual noted the "Permissible ambient temperature was +15 degrees Celsius (C) to +37 degrees C" and the "Permissible relative air humidity was less than or equal to 85% at +30 degrees C." 2. Review of the quality control records showed there were no temperature or humidity logs for the preparation room. 3. On 02/06/2025 at 1:40 PM, the Laboratory Director stated they did not take the temperature or humidity of the preparation room.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the quality control logs, the procedure manual, and interview, the laboratory failed to perform and document the instrument to instrument comparison of 18 modified Sony Flow Cytometers used for Mediator Release Test (MRT) for food sensitivities at least twice annually from 11/08/2022 to 02/06/2025. Findings: 1. Review of the quality control documentation showed there was no documentation of an instrument to instrument comparison. 2. Review of the procedure manual showed there was no procedure on instrument to instrument comparisons. 3. On 02/06/2025 at 2:15 PM, the Laboratory Director stated they did not do an instrument to instrument comparison and did not have a procedure on it.
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 review of personnel records, and interview, the laboratory failed to provide the college degree and foreign equivalency evaluation document for 1 (D) of 4 (A - D) Testing Personnel. (See D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each

	specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records, and interview, the laboratory failed to provide the college degree and foreign equivalency evaluation document for 1 (D) of 4 (A - D) Testing Personnel. Findings: 1. Review of personnel records for Testing Personnel D revealed he had an Advanced Technical Diploma in Medical Laboratory Technology. 2. Review of the website for the college where Testing Personnel D obtained his diploma read, "Upon completion of the program and meeting eligibility requirements, including the attainment of an aligned industry credential, students may be awarded credits toward an Associate Degree . . . ." 3. On 02/19/2025 at 12:39 PM, the Laboratory Director said it may be challenging Testing Personnel D to obtain his transcripts, and would check if he had foreign equivalency evaluation. No foreign equivalency was received.