Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2284653	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Biodynamics Inc	7495 New Horizon Way #110, Frederick, MD	

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
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 review of the procedure and interview with the laboratory director (LD) and general supervisor (GS), the laboratory failed to perform a negative extraction control to monitor for potential contamination in the specimen processing procedure for the laboratory's polymerase chain reaction (PCR) assay. Findings: 1. The laboratory performed a real time PCR assay that included fixation, extraction, library preparation, and purification of nucleic acids found in patient whole blood specimens. 2. The "Assay Setup" section of the procedure titled "Real Time PCR Detection of EpiSwitch Libraries" described how to set up each plate and add "the respective sample library, extraction blank (if applicable), or synthetic standards" according to the plate layout. 3. During the survey on 04/24/2024 at 10:50 AM, the LD and GS confirmed that though they had run extraction blanks in the past, they were not currently running an extraction blank with patient specimens to monitor potential contamination of the specimen processing procedure.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance record review and interview with the general supervisor (GS), the laboratory failed to evaluate and define the relationship between test results using different instruments twice a year, and to document all test result comparison activities. Findings: 1. The laboratory performs polymerase chain reaction (PCR) testing using three Bio-Rad CFX qPCR System thermocyclers labeled "qPCR-001," "qPCR-002," and "qPCR-003." 2. Procedure manual review showed that the laboratory had no written policy for performing and evaluating the correlations between the three analyzers twice a year; and 3. The procedure should include, but is not limited to: how often split samples will be tested, what the acceptable limits of the comparisons are, and remedial actions to be taken when the results are not within acceptable limits. 4. During an interview on 04/24/2024 at 3:00 PM, the GS confirmed that there was no documentation that test result comparisons had been performed between the three analyzers.
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 review of testing personnel (TP) credentials and interview with the laboratory director (LD), the LD failed to ensure that TP with degrees from foreign institutions had an evaluation of their credentials to determine United States equivalency. Findings: 1. The laboratory currently has three TP listed on the "Laboratory Personnel Report" (CMS-209). 2. A review of TP credentials showed that the degree for TP #2 was earned in Romania. There was no foreign credential equivalency evaluation present at the time of the survey. 3. During an interview on 04/24/2024 at 3:00 PM, the LD confirmed that the laboratory had not completed a foreign credential equivalency evaluation for TP #2 to determine if they were qualified to perform high complexity testing.