Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2161973	02/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Jellyfish Medical Management Llc	2 Hughes Ste 175, Irvine, CA	

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
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 review of the laboratory's temperature records, and interview with the laboratory personnel, it was determined that the laboratory failed to follow their defined criteria for temperature monitoring and recording. The findings included; a. Review of a temperature chart, :AFMC Andrology Lab Daily QC" for the month of Jan. 2020. b. On the Daily QC chart listed "Room T" 72-82 F; Humidity 20-60 %; "Heat block" (36.5 -37.5 oC; "Refrigerator" 2-4 oC; "freezer" -15 - -18oC; "incubator" 35-37.5 oC. c. There were a total of 12 days the laboratory performed semen analyses onsite as listed in item d, "Summary temperature chart". d. Summary of the temperature charts in 2020 with corresponding records related to its temperature parameters on the day semen analyses were performed as follow: Rm T = room temperature; F = Fahrenheit; oC = Celsius Criteria for: Room T (72 -82 F); Heat Block (36.5-37.5 oC); Freezer (-15 to -18 oC); incubator (35-37.5 oC) Date Rm T Heat block freezer incubator 01/03 19.8 38.0 -15,2 01/08 19.7 38.0 -14.8 3 (?) 01/10 20.0 38.0 -16.7 01/13 17.8 38.0 -11.2 01/16 16.4 38.0 -15.1 01/17 15.4 38.0 -10.1 01 /21 16.4 38.0 -17.8 01/23 16.1 38.0 -10.0 01/24 16.4 38.0 -12.9 01/28 17.8 38.0 -18.3 01/29 15.9 38.0 -10.2 01/30 16.8 38.0 -9.8 e. The laboratory established the acceptable "Room T" was between 72-82 F (Fahrenheit), all of the total of 12 days temperature recorded were between 15 and 20 F, which were all outside of the

	established 72-82 F, f. The laboratory established the acceptable "Heat block" was between 36.5-37.5 oC, all of the total of 12 days temperature recorded were 38.0, which were all outside of the established between 36.5-37.5 oC, g., The laboratory established the acceptable "freezer" was between -15 to -18 oC, 7 out of of the total of 12 days temperature recorded were between -9.8 and -14.8 oC which were outside of the established acceptable temperature between -15 to -18 oC. h. The laboratory established the acceptable "Incubator" temperature was between 35--37.5 oC. The testing personnel addressed that the incubator is used for keeping the semen specimen under proper temperature environment while waiting for liquefactions. i. There were no temperature recorded incubator column for the total 12 days except a "3" written on 01/08. j. The temperature records in the January 2020 month showed many temperature records outside of the acceptable temperature ranges.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the facility, review of the laboratory's temperature records, and interview with the laboratory personnel, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when the temperature monitoring and recording do not meet the laboratory's verified or established performance specifications. The findings included; a. Review of a temperature chart, :AFMC Andrology Lab Daily QC" for the month of Jan. 2020. b. The temperature records in the January 2020 month showed many temperature records outside of the acceptable temperature ranges c. The laboratory failed to document all corrective action taken when the temperature monitoring and recording do not meet the laboratory's verified or established performance specifications, see D-5413
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, review of laboratory records including temperature charts, CMS 209, and interview of the laboratory testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the

	quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory failed to maintain accurate and reliable daily temperature monitoring, reading, and evaluations, see D-5413 b. The laboratory failed to effectively correct, and take the corrective actions when failures of the daily temperature monitoring and evaluating, see D-5781
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, review of laboratory records including temperature charts, CMS 209, and interview of the laboratory testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system, see D-5413, D-5781 and D-6170
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, review of laboratory records including temperature charts, the survey documents, including but are not limited to the director attestation form, and interview of the laboratory testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics were identified. The findings included: a. The laboratory failed to ensure that all necessary remedial actions were taken and documented, see D-5781 and D-6170
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 review of the laboratory's CMS 209 Laboratory Personnel Report (CLIA), and interview with the testing personnel and the laboratory director, it was determined that the laboratory failed to employ a qualified high complexity testing personnel to perform its semen analyses. The findings included: a. The laboratory perform semen analyses and report the following results, but are not limited to, motility, morphology,

	count, forward progress, etc. b. The testing personnel qualification for high complexity testing 42 CFR part 493.1489 requires: a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required: and, (b) ... c. The laboratory listed SH, a high complexity testing personnel in its CMS 209 "Laboratory Personnel Report (CLIA)", who does not hold a laboratory certified license by the State of California. d. This testing person, SH, is not qualified to perform semen analyses according to 42 CFR part 493.1489 (a). e. The laboratory failed to employ a qualified personnel to perform semen analyses, a high complexity testing.