Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0710658	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lifeline Medical Associates, Llc	2 Princess Road, Lawrenceville, NJ	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Patient Testing Records and interview with the Testing Personnel (TP), the laboratory failed to retain working records for Semen Counts, Morphology and Motility for Semen Analysis testing from 3/23/17 to the date of survey. The finding includes: 1. The TP stated he wrote results on a piece of paper but didn't keep the paper. 2. The TP confirmed on 1/23/19 at 1:00 pm that patient test records were not retained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on one of one TP in the calendar years 2017 and 2018. The finding includes: 1. The CA did not include assessment of test performance through testing previously analyzed samples, internal blind testing samples or external proficiency testing samples. 2. The TP confirmed on 1/23/19 at 1:15 pm that CA was not done correctly.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Semen Motility (SM) twice annually in the calendar years 2017 and 2018. The TP confirmed on 1/23/19 at 2:00 pm that the laboratory did not verify the accuracy of SM twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the written procedures for Semen Analysis tests from 3/22/17 to the date of survey. The findings include: 1. The PM stated to "spin semen sample at 600g but the TP stated the laboratory spun samples at 1400 rpms. a. The TP did not know if 1400 rpms was equivalent to 600g. 2. The PM stated "To repeat the count in two other strips of 10 and determine the average. Repeat the procedure on another counting chamber . The final number is the average of all counts" but there was no documented evidence the count was done more than one time. 3. The PM stated " When no sperm cells are visible, the specimen is centrifuged, and the pellet microscopically analyzed for the presence of any sperm but the TP stated the laboratory did not perform the above procedure for Azoospermia. 4, The PM stated for Sperm Motility (SM): A vital stain is used to differentiate viable sperm for nonviable sperm if motility is less that 30% but there was no vital stain observed in the laboratory. a. The TP stated the laboratory did not use a vital stain for SM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for concentration of the semen sample from 3/23/17 to the date of survey. The TP confirmed on 1/23/19 at 2: 10 pm that the laboratory did not establish the above procedure.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the FR for Semen analysis testing included all required information from June 2018 to the date of the survey. The findings include: 1. The FR did not have: a. The name and address of the laboratory location where tests were performed. b. The FR did not have the "Test Report Date". 2. The TP confirmed on 1/23/19 at 2:30 pm that the laboratory did not have all the required information on the FR.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for Semen Analysis tests from 3/23/17 to the date of survey. The findings include: 1. The TP stated the laboratory used the RI in the Procedure Manual (PM). 2. The RI in the PM differed from the FR as follows: a. FR Volume: >=2.0 Milliliters (ml) but PM stated 1-6 ml . b. FR Viscosity: 0-4 but PM stated 3-5 centimeters (cm). c. FR Liquefaction time: completed within 60 minutes but PM stated if liquefaction greater than 30 minutes record on report but a review of reports revealed liquefaction

	was reported as complete or incomplete. d. FR pH: >=7.2 but PM stated 7.2 - 8.0. 3. The TP confirmed on 1/23/19 at 1:00 pm that the source of the RI was unknown.