Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2174455	07/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Center For Male Infertility (Cmi)	4809 E 89th St S, Ste 100, Tulsa, OK	

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	The initial survey was performed on 07/13/2021. The findings were reviewed with the laboratory director, laboratory manager, the testing person, and the operations manager during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1441; D6076: Laboratory Director
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory director and laboratory manager, the laboratory director or designee failed to sign proficiency testing attestation statements for 2 of 3 events. Findings include: (1) Surveyor #2 reviewed 2020 and 2021 proficiency testing records and identified the following for 2 of 3 events: (a) Third 2020 Chemistry (Q3) Event - The attestation statement had not been signed by the laboratory director or designee; (b) First 2021 Chemistry (Q1) Event - The attestation statement had not been signed by the laboratory director or designee. (2) Surveyor #2 reviewed the findings with laboratory director and laboratory manager, who both stated to surveyor #2 on 07/13/2021 at 09:50 am, the attestation

	statements had not been signed by the laboratory director or designee as indicated above.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, FDA database, and interview with the laboratory director and laboratory manager, the laboratory failed to establish the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals for the Halotech Halosperm G2 test not cleared or approved by the FDA. Findings include: (1) On 07/13/2021 at 10:50 am, the laboratory director and laboratory manager stated to the surveyors the lab began using the Halotech Halosperm G2 test for assessing sperm DNA fragmentation on 12/09/2019; (2) Surveyor #1 had not encountered this test previously and therefore, attempted to verify the classification of the test. Since classification of test systems are performed by the FDA (Food and Drug Administration), the surveyor reviewed the FDA test classification database. The database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity or LDT-Laboratory Developed Test); (3) On 07/13/2021 at 11:15 am, surveyor #1 explained to the laboratory director and laboratory manager the test was classified as LDT, which required the performance specifications of accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values), as applicable, be established; (4) Surveyor #1 reviewed records for the test system and there was no evidence the accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values), as applicable, had been established; (5) Surveyor #1 reviewed the findings with the laboratory director and laboratory manager. Both stated there were no records to prove the precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals had been established for the test; (6) The following were examples of patient testing performed: (a) Patient #57388 - testing performed on 12/09/2019 (b) Patient #57818 - testing performed on 12/10/2019 (c) Patient #61060 - testing performed on 01/31 /2020 (d) Patient #63856 - testing performed on 04/08/2020 (e) Patient #65970 - testing performed on 07/27/2020 (f) Patient #71066 - testing performed on 07/09/2020 (g) Patient #72996 - testing performed on 07/30/2020 (h) Patient #81156 - testing performed on 11/09/2020 (i) Patient #81913 - testing performed on 11/19/2020 (j) Patient #87544 - testing performed on 01/29/2021 (k) Patient #88575 - testing performed on 02/08/2021 (l) Patient #89718 - testing performed on 02/25/2021 (m) Patient #94509 - testing performed on 04/13/2021 (n) Patient #95223 - testing

	performed on 04/29/2021 (o) Patient #99029 - testing performed on 06/08/2021 (p) Patient #99818 - testing performed on 06/21/2021 (q) Patient #101244 - testing performed on 06/30/2021
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to perform function checks as defined by the manufacturer. Findings include: (1) On 07/13/2021 at 09:20 am, the laboratory manager stated to surveyor #2 the laboratory used the Eppendorf Centrifuge 5702 to process patient specimens; (2) Surveyor #2 reviewed the manufacturer's instructions titled, "Original instructions" for the centrifuge used to process the specimens. The section titled, "8 Maintenance" instructions stated the following: (a) "8.1 Service - We recommend to have the centrifuge and the associated rotors checked by Technical Service during a service at least every 12 months." (3) Surveyor #2 asked the laboratory manager for the function checks records. The laboratory manager stated on 07/13/2021 at 10:50 am the laboratory had not had the centrifuge checked since patient testing began on 12/05/2019.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, laboratory manager, and the testing person, the laboratory failed to perform a negative and positive control material 17 of 17 days of patient testing reviewed. Findings include: (1) On 07/13/2021 at 10:50 am, the laboratory director and laboratory manager stated to the surveyors the lab began using the Halotech Halosperm G2 test was for assessing sperm DNA fragmentation on 12/09/2019; (2) Surveyor #1 reviewed records of testing from 12/09/2019 through the day of the survey and asked the laboratory director, laboratory manager, and testing person if negative and positive QC (Quality Control) materials were performed each day of patient testing. All stated the following on 07/13/2021 at 11:30 am: (a) QC slides were prepared with each new lot number of test kits, but the laboratory had not maintained documentation of this; (b) Negative and Positive QC materials had not been performed each day of patient testing. (3) Refer to D5423 for patient testing performed.
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 a review of records, FDA database, and interview with the laboratory director, laboratory manager, and the testing person, the laboratory director failed to provide overall management and direction for high complexity testing for the Halotech Halosperm G2 test. Findings include: (1) The laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Refer to D6086; (2) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the laboratory director and laboratory manager, the laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The laboratory failed to ensure the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals had been established for the Halotech Halosperm G2 test not cleared or approved by the FDA. Refer to D5423.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of records and interview with the laboratory director, laboratory manager, and the testing person, the laboratory director failed to ensure quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure negative and positive control materials had been performed each day of patient Halotech Halosperm G2 testing. Refer to D5449.