Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2084784	09/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Center For Men's Health	1601 Yakima, Broken Arrow, 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 recertification survey was performed on 09/28/2020 and 09/29/2020. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1240; D5300: Preanalytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant
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 the technical consultant, the laboratory director or designee failed to sign a proficiency testing attestation statement for 2 of 7 events. Findings include: (1) On 09/29/2020, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following for 2 of 7 events: (a) Second 2019 Chemistry Core Event - The attestation statement had not been signed by the laboratory director; (b) Second 2020 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director. (2) The surveyor

	reviewed the findings with the technical consultant. The technical consultant stated on 09/29/2020 at 10:50 am the attestation statements had not been signed by the laboratory director or designee.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to monitor and evaluate the overall quality of preanalytic systems. Findings include: (1) The laboratory failed to follow manufacturer's instructions for storing Vitamin D samples. Refer to D5311; (2) The laboratory failed to have an ongoing mechanism for performing preanalytic quality assessment. Refer to D5391.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for storing Vitamin D samples. Findings include: (1) On 09/28/2020 at 02:00 pm, the technical consultant stated the following to the surveyor: (a) Vitamin D was performed using the Tosoh analyzer beginning 09/18/2019. (2) The surveyor asked testing person #1 if the laboratory batched any tests performed on the Tosoh analyzer. Testing person #1 stated on 09/29/2020 at 12:10 pm, the laboratory batched Vitamin D patient testing once or twice each week and stored the patient specimens in the laboratory refrigerator with a range of 2-8C; (3) The surveyor reviewed the manufacturer's specimen collection and handling instructions for Vitamin D testing which stated the following: (a) "Samples may be stored at 2-8 C for up to 48 hours prior to analysis. If the analysis cannot be done within 48 hours, the sample should be stored frozen at -20 C or below for up to 60 days." (4) The surveyor then reviewed patient Vitamin D testing records between 09/01/2020 and 09/30/2020 and identified the samples had been stored at 2-8 degrees C for more than 48 hours as follows: (a) Patient Accession#4586 was collected on 09/10/2020 and tested on 09/15/2020; (b) Patient Accession#4588 was collected on 09/10/2020 and tested on 09/15/2020; (c) Patient Accession#4590 was collected on 09/10/2020 and tested on 09/15/2020; (d)

	Patient Accession#4591 was collected on 09/10/2020 and tested on 09/15/2020; (e) Patient Accession#4585 was collected on 09/11/2020 and tested on 09/15/2020; (f) Patient Accession#4587 was collected on 09/11/2020 and tested on 09/15/2020; (g) Patient Accession#4589 was collected on 09/11/2020 and tested on 09/15/2020; (h) Patient Accession#4592 was collected on 09/11/2020 and tested on 09/15/2020; (i) Patient Accession#4660 was collected on 09/16/2020 and tested on 09/22/2020; (j) Patient Accession#4661 was collected on 09/16/2020 and tested on 09/22/2020; (k) Patient Accession#4662 was collected on 09/16/2020 and tested on 09/22/2020; (l) Patient Accession#4659 was collected on 09/17/2020 and tested on 09/22/2020; (m) Patient Accession#4658 was collected on 09/18/2020 and tested on 09/22/2020; (n) Patient Accession#4760 was collected on 09/23/2020 and tested on 09/29/2020; (o) Patient Accession#4766 was collected on 09/23/2020 and tested on 09/29/2020; (p) Patient Accession#4769 was collected on 09/23/2020 and tested on 09/29/2020; (q) Patient Accession#4761 was collected on 09/24/2020 and tested on 09/29/2020; (r) Patient Accession#4768 was collected on 09/23/2020 and tested on 09/29/2020; (s) Patient Accession#4770 was collected on 09/23/2020 and tested on 09/29/2020; (t) Patient Accession#4773 was collected on 09/23/2020 and tested on 09/29/2020; (u) Patient Accession#4762 was collected on 09/24/2020 and tested on 09/29/2020; (v) Patient Accession#4764 was collected on 09/25/2020 and tested on 09/29/2020; (w) Patient Accession#4765 was collected on 09/25/2020 and tested on 09/29/2020; (x) Patient Accession#4771 was collected on 09/25/2020 and tested on 09/29/2020. (5) The surveyor reviewed the findings with the technical consultant. The technical consultant and testing person #1 both stated on 09/29/2020 at 01:30 pm, the laboratory stored patient samples in the laboratory refrigerator and not according to manufacturer's instructions as indicated above.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to have an ongoing mechanism for performing preanalytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing preanalytic quality assessment because the laboratory failed to follow the manufacturer's instructions for storing Vitamin D samples. Refer to D5311.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of written procedures and interview with the technical consultant, the laboratory director failed to approve, sign, and date procedures before beginning patient testing. Findings include: (1) On 09/28/2020 at 02:00 pm, the technical

	consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer beginning on 09/15/2019; (b) Estriadiol, Ferritin, FSH (Follicle Stimulating Hormone), FT3 (Free Triiodothyronine) , FT4 (Thyroxine), LH (Luteinizing Hormone), Prolactin, PSA (Prostate Specific Antigen), SHBG (Sex Hormone Binding Globulin), Testosterone, TSH (Thyroid Stimulating Hormone), and Vitamin D was performed using the Tosoh analyzer beginning 09/18/2019. (2) The surveyor reviewed the procedures for CBC testing and the Estriadiol, Ferritin, FSH, FT3, FT4, LH, Prolactin, PSA, SHBG,Testosterone, TSH, and Vitamin D testing. There was no evidence the procedures had been signed and dated as approved by the laboratory director before the laboratory began performing patient testing; (2) The surveyor reviewed the procedures with the technical consultant, who stated on 09/29/2020 at 10:35 am the procedure for CBC testing had not been signed and dated by the laboratory director until 09/25/2020 and the procedure for testing on the Tosoh analyzer had not been signed and dated by the laboratory director until 11/10/2019.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for verifying flagged results. Findings include: (1) On 09/28/2020 at 02:00 pm, the technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer beginning on 09/15 /2019; (b) Manual differential testing was not performed in house. If a manual differential was required, the specimen would be sent to a reference laboratory. (2) On 09/20/2020, the surveyor reviewed the manufacturer's instructions for verifying flags obtained on the analyzer. For AG flags, the instructions stated, "Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc". In addition, the instructions stated, "Check Smear. etc"; (3) The surveyor randomly reviewed 5 patient records which contained AG flags from CBC testing performed between 09/10/2020 through 09/28/2020. For 1 of 5 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the AG flag. The findings for the record was: (a) Patient testing was performed on 09/28/2020, with an AG flag obtained next to Platelet. (4) The surveyor reviewed the record with the technical consultant who stated on 09/29/2020 at 11:35 am the flag obtained for the above patient had not been verified as required by the manufacturer.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory failed to verify the normal reference range and failed to ensure the verified reportable range was used by the laboratory. Findings include: (1) On 09/28/2020 at 02:00 pm, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer beginning on 09/15 /2019; (2) The surveyor reviewed the performance specification records, and was not able to find evidence that the Normal Reference Range had been verified; (3) In addition, the surveyor identified the following Reportable Ranges had been demonstrated by the laboratory: (a) Hemoglobin 0 - 22 g/dL; (b) Hematocrit 0 - 58.6%. (4) The surveyor then requested documentation to show the reportable ranges that had been programmed into the analyzer, which showed the laboratory was using the following reportable ranges: (a) Hemoglobin 0.1 - 25 g/dL; (b) Hematocrit 10 - 60%. (5) The surveyor reviewed the records with the technical consultant, who stated to the surveyor on 09/28/2020 at 2:45 pm the Normal Reference Range had not been verified by the laboratory, and the laboratory was not utilizing their demonstrated reportable ranges as indicated above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 technical consultant, the laboratory failed to have quality control procedures that monitored the accuracy and precision of the analytic process for hematology testing for 3 of 3 lot numbers. Findings include: (1) On 09/28/2020 at 02:00 pm, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer beginning on 09/15/2019; (2) On 09/28/2020 at 02:10 pm, the technical consultant stated the following to the surveyor: (a) Three levels of quality control materials were tested each morning; (b) Laboratory established quality control ranges were used to determine acceptability of control results. (3) The surveyor reviewed quality control records for level 1 lot #91980710, level 2 lot #91980711, and level 3 lot #91980712. For 3 of 3 lot numbers used from 09/18/2019 through 10/22/2019, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances using the laboratory's established ranges for each analyte tested (e.g., White Blood Cell, Hemoglobin, Platelet, etc.); (4) The surveyor requested

	2019 Levey-Jennings graphs that could be printed from the analyzer. The technical consultant was able to print the graphs for the above lot numbers and stated on 09/28 /2020 at 03:10 pm, the laboratory did not routinely print the graphs and previous lot numbers were not available for review; (5) Therefore, the surveyor was not able to review quality control records that included the laboratory established ranges for lot numbers in use after the above lot numbers.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure quality laboratory services for all aspects of test performance, which includes the preanalytic phase of testing were provided. Refer to D6007; (2) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to provide quality laboratory services for all aspects of test performance, which includes the preanalytic phase of testing. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for manufacturer's instructions for storing Vitamin D samples. Refer to D5311.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure an effective mechanism for performing preanalytic quality assessment. Refer to 5391.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the technical consultant, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the manufacturer's instructions were followed for storing Vitamin D samples. Refer to D5311.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 1 of 1 testing persons.

	Findings include: (1) On 09/29/2020, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #1 - The initial training for this person was completed on 09/16/2019. There was no evidence that a semiannual evaluation had been performed (due 03/2020); (2) The surveyor reviewed the records with the technical consultant who stated on 09/29/2020 at 09:45 am there were no records to prove the above person had been evaluated semiannually.