Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2084784	05/19/2022
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 05/19/2022. The findings were reviewed with testing person #1 and the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 a review of the policy and procedure manual and interview with the technical consultant and testing person #1, the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing for four of five patient reports; and failed to follow written procedures for CBC quality control lots for six of six lot numbers. Findings include: HEMATOLOGY RESULT FLAGGING PROCEDURE (1) On 05/19/2022 at 10:20 am, the technical consultant stated the following: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 hematology analyzer. (2) A review of the written procedures titled, "Laboratory Manual" under the hematology procedure, titled, "Hematology Result Flagging Procedure" stated the following: (a) "AG The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter the WBC count, but may result in decrease platelet count" (b) "If any of these flags are observed, perform the following steps" (i) "1. Check specimen for clot (ii) "2. Rerun unclotted specimen specimen to see if the flag remains" (iii) "3. If flag remains" (aa) "Print CBC results and place in folder" (bb) "Do not verify" (cc) "Send CBC to reference lab to perform" (dd) "Report reference lab results" (ee) "Place a copy of ref lab results in folder" (3) A review of five patient records that had been tested on 02/22

	/2021, 03/22/2021, 05/05/2021, 05/11/2021, and 08/20/2021 revealed for four of five patient records there was no evidence the laboratory staff followed their written procedure as follows: (a) Patient reported on 02/22/2021 at 12:20 pm - No evidence the laboratory sent the AG flag to the reference laboratory; (b) Patient reported on 03 /22/2021 at 12:08 pm - No evidence the laboratory sent the AG flag to the reference laboratory; (c) Patient reported on 05/05/2021 at 12:18 pm - No evidence the laboratory sent the AG flag to the reference laboratory; (d) Patient reported on 08/20 /2021 at 10:43 am - No evidence the laboratory sent the AG flag to the reference laboratory; (3) The findings were reviewed with testing person #1 who stated on 05/19 /22 at 03:30 pm that the procedure had not been followed as indicated above. NEW LOT OF QUALITY CONTROL (1) On 05/19/2022 at 10:20 am, the technical consultant stated the following: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 hematology analyzer; (b) Three levels of EightCheck-3WP-X-tra (Low, Normal, High) QC (Quality Control) materials were performed each day of patient testing. (2) A review of the written procedures titled, "Laboratory Manual" under the hematology procedure, titled, "E. Starting a New Lot of Controls" stated the following: (a) "Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot.". (3) A review of quality control records revealed for six of six lot numbers revealed there was no evidence the laboratory staff followed their written procedure as follows: (a) Lot# 20260710, 20260711, 20260712 was put into use on 02 /10/2022 after four parallel runs once each day; (b) Lot# 21100710, 21100711, 21100712, was put into use on 04/29/22 after four parallel runs once each day. (4) The findings were reviewed with the technical consultant who stated on 05/19/22 at 03:20 pm that the procedure had not been followed as indicated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the technical consultant, the laboratory failed to follow their written protocol for ensuring the centrifuge used to process chemistry and endocrinology samples was functioning properly for one of two function checks performed. Findings include: (1) On 05/19 /2022 at 10:30 am, the technical consultant stated the following: (a) The laboratory processed chemistry and endocrinology specimens using the LabCorp Model 642 E Centrifuge at 8000 rpm (revolutions per minute) for 10 minutes. (2) A review of 2021 and 2022 centrifuge records revealed the following for one of two checks performed: (a) The centrifuge had been checked at five minutes on 05/06/2021. (3) The findings were reviewed with the technical consultant who stated on 05/19/2022 at 12:35 pm, the centrifuge function check had not been checked at 10 minutes as indicated above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months for four of four analytes. Findings include: (1) On 05/19/2022 at 10:15 am, the technical consultant stated: (a) Ferritin, Follicle Stimulating Hormone, Prolactin, PSA (Prostate-Specific Antigen) testing were performed using the Tosho analyzer. (2) A review of 2021 and 2022 calibration verification records revealed the calibration procedures for the above analytes had been performed with two levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of calibration verification records from January 2021 through March 2022 revealed that calibration verification had not been performed between 06/06 /2021 and 03/22/2022; (4) The records were reviewed with the technical consultant who stated on 05/19/2022 at 03:00 pm, calibration verification procedures had not been performed every six months.
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 and testing person #1, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for Chemistry and Endocrinology testing for two of two lot numbers. Findings include: (1) On 05/19 /2022 at 10:50 am, the technical consultant stated the following: (a) Estradiol, Ferritin, (FSH) Follicle Stimulating Hormone, (LH) Luteinizing Hormone, Prolactin, PSA (Prostate-Specific Antigen), (SHBG) Sex Hormone Binding Globulin, (TSH)Thyroid Stimulating Hormone, and (FT4) thyroxine were performed on the Tosho analyzer; (b) Two levels of Bio-Rad Liquichek Immunoassay Plus Control were performed each day of patient testing; (c) Established ranges were used for determining acceptability of QC results. (2) A review of QC records which included documentation of establishing QC ranges, Levey-Jennings graphs, and cumulative data for level 1 lot# 85271 and level 3 lot# 85273 used during the review period of 07/01/2021 through 05 /19/2022 (day of the survey) revealed that, although the laboratory had established a mean an a 2 SD range, the manufacture's range was in use during the review period; (3) The records with the technical consultant and testing person #1. Both stated on 05 /19/2022 at 03:45 pm, the manufacturer's ranges were used to evaluate QC results.