

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1065032	(X3) Date Survey Completed 03/30/2023
Name of Provider or Supplier Fem Centre	Street Address, City, State 6221 Colleyville Blvd, Suite 100, Colleyville, TX	
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 laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) testing records, laboratory's CMS (Centers for Medicare & Medicaid Services) 209 form, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2022 (Event 1, 2, 3). Findings included: 1. Review of the laboratory's proficiency testing policy revealed: "Policy: Proficiency Testing will consist of the following: A. Personnel performing testing materials 1. The personnel performing the proficiency tests will be the medical laboratory technologists who perform general patient samples. 2. The proficiency test samples should be integrated into the routine workload." 2. Review of the CAP testing records revealed the following instructions: "REGULATORY INFORMATION Per CLIA, as published by the United States Federal Register Proficiency Testing (PT) specimens must be tested with the laboratory's regular workload, using routine methods, and testing the PT specimens the same number of times it routinely tests patient specimens" 3. Further review of the CAP testing records revealed the laboratory participated in the following events: 2022: General Chemistry; Events: C-A 2022, C-B 2022, C-C 2022 Hematology Auto Differentials; Events FH2-A 2022, FH2-B 2022, FH2-C 2022 Ligand; Events K-A 2022, K-B 2022, K-C 2022 Further review of the PT records revealed Testing Person 1 participated in all the above PT events. 3.</p>

Review of the laboratory's CMS 209 form revealed 2 Testing Persons (TP) were listed as performing all moderate complexity tests performed by the laboratory. Testing Person-2 (TP-2) Hire date: 07/2008 TP-2 participated in testing patient specimens and did NOT participate in any of the above listed PT events for 2022. 4. During an interview on 03/30/2023 at 11:40 am, the Technical Consultant (who was also Testing Person-1) confirmed the above findings. The laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing.

D2009

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, College of American Pathologists (CAP) instructions, CAP proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 chemistry events in 2022 (Event C-B 2022) and 1 of 3 ligand events in 2022 (Event K-C 2022). 1. Review of the laboratory's PT policy revealed: 1. Review of the laboratory's proficiency testing policy revealed: "Policy: Proficiency Testing will consist of the following: A. Personnel performing testing materials 1. The personnel performing the proficiency tests will be the medical laboratory technologists who perform general patient samples. 2. The proficiency test samples should be integrated into the routine workload ... 7. Sign and retain the Attestation Statement." 2. Review of CAP instructions revealed: "Attestation/Use of Other Form Attestation Statement As stated in the February 28, 1992 United States Federal Register under Subpart H 493.801(b)(1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign on the result form. You may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes." 3. Review of chemistry PT records for Event C-B 2022 revealed the laboratory director and testing person 1 failed to sign the attestation statement. Review of ligand PT records for Event K-C 2022 revealed the laboratory director and testing person 1 failed to sign the attestation statement. 4. During an interview on 03/30/2023 at 11:40 am, the Technical Consultant (who was also Testing Person-1) confirmed the above findings.

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 review of laboratory's quality control (QC) policy, BIO-RAD control material manufacturer's instructions, assignment of value sheets, ADVIA Centaur XP QC data, and in interview with staff, the laboratory failed to ensure their control procedures detected immediate error for 1 of 1 set of current lot numbers. Findings: 1. Review of the laboratory's policy "VERIFICATION OF MANUFACTURER'S ESTABLISHED MEANS AND RANGES" revealed: "Prior to introducing a new lot of BioRad Liquichek Immunoassay Plus Control or Horiba Pentra Carbon Dioxide control, both lots (old and new) must be run in parallel for 3 days to verify the manufacturer's published means and ranges. ESTABLISHING MEAN AND RANGES ON UNASSAYED CONTROL MATERIAL With each new lot of Bio-Rad Liquichek Immunoassay Plus Control and Siemens Vitamin D QC, controls will be run daily for a total of 20 replicates prior to use as daily QC. From these results the FEM Centre mean and +/- 2 SD ranges will be calculated and put into use for daily QC requirements. These means should fall within manufacturer's means [sic] The manufacturers stated ranges will be used until enough data points are collected and calculated to establish the FEM Centre ranges." 2. Review of BIO-RAD Liquichek Immunoassay Plus Control manufacturer's instructions (package insert) revealed: "ASSIGNMENT OF VALUES The means and values and corresponding +/-3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product ... It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control." Further review of the Assignment of Values revealed the following sampling of analyte QC ranges: Liquichek Immunoassay Plus Control Level 1 Lot #85331; expiration date: 08/31/2024 Level 2 Lot #85332; expiration date: 08/31/2024 Level 3 Lot #85333; expiration date: 08/31/2024 Cortisol (COR) Level 1 Mean: 4.44; Range: 3.26-5.62 Level 2 Mean: 23.7; Range: 18.4-29.1 Level 3 Mean: 34.2; Range: 26.5-41.8 Dehydroepiandrosterone-Sulfate (DHEA) Level 1 Mean: 79.6; Range: 58.5-101 Level 2 Mean: 129; Range: 97.7-160 Level 3 Mean: 442; Range: 337-547 Follicle Stimulating Hormone (FSH) Level 1 Mean: 6.83; Range: 5.39-8.27 Level 2 Mean: 17.6; Range: 14.5-20.8 Level 3 Mean: 40.5; Range: 33.6-47.3 Luteinizing Hormone (LH) Level 1 Mean: 3.42; Range: 3.42; Range: 2.76-4.08 Level 2 Mean: 18.5; Range: 15.0; Range: 15.0-22.1 Level 3 Mean: 63.1; Range: 50.9-75.4 Progesterone (PRGE) Level 1 Mean: 1.06; Range: 0.645-1.47 Level 2 Mean: 8.85; Range: 6.66-11.0 Level 3 Mean: 18.8; Range: 14.3-23.2 A handwritten note at the bottom of the sheet stated: "Due to shipment issues - ranges specific to FEM Centre will be established after 2 weeks of Data [sic]" 3. Review of ADVIA Centaur XP endocrinology/chemistry analyzer QC data (random review 11/2022 through 03/2023) revealed the ranges used did not detect immediate error, as follows (random sampling of analytes): Liquichek Immunoassay Plus Control (put into use 11/15/2022): Level 1 Lot #85331; expiration date: 08/31/2024 Level 2 Lot #85332; expiration date: 08/31/2024 Level 3 Lot #85333; expiration date: 08/31/2024 Laboratory Cortisol (COR) ranges used for day-to-day acceptability: Level 1 Mean: 4.44; Range: 3.3-5.6 Level 2 Mean: 23.70; Range: 18.4-29.1 Level 3 Mean: 34.20; Range: 26.6-41.9 Dehydroepiandrosterone-Sulfate (DHEA) Level 1 Mean: 79.60; Range: 58.4-100.9 Level 2 Mean: 129.00; Range: 97.9-160.2 Level 3 Mean: 442.00; Range: 337.0-547.0 Follicle Stimulating Hormone (FSH) Level 1 Mean: 6.83; Range: 5.4-8.3 Level 2 Mean: 17.60; Range: 14.5-20.8

Level 3 Mean: 40.50; Range: 33.7-47.4 Luteinizing Hormone (LH) Level 1 Mean: 3.42; Range: 3.42; Range: 2.8-4.1 Level 2 Mean: 18.50; Range: 15.0; Range: 15.0-22.1 Level 3 Mean: 63.10; Range: 50.9-75.4 Progesterone (PRGE) Level 1 Mean: 1.06; Range: 0.6-1.5 Level 2 Mean: 8.85; Range: 6.7-11.0 Level 3 Mean: 18.80; Range: 14.4-23.3 The laboratory's QC ranges were too wide to detect immediate error. 4. During an interview on 04/30/2023 at 2:45 pm, the Technical Consultant confirmed she had not established QC ranges for the laboratory and was using the manufacturer's ranges at 3SDs.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, ADVIA Centaur quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 60 of 60 patients in 2022 and 2023 (November 2022 through March 2023 random review). Findings included: 1. Review of laboratory's policy titled "Quality Assessment" revealed: "Quality Control Remedial Actions Quality controls normally fall within the limits of test specifications. Those outside set into motion the dictated steps for correction. The following quality control remedial actions are outlined. Observed control values acceptable? Yes report patient results No Controls, reagents, calibrators and/or kits expired? Yes Retest with acceptable materials No Rerun unacceptable controls; Acceptable? Yes Report patient results No Run new control, same lot#; Acceptable? Yes Report patients Calibrate and/or perform maintenance; Acceptable? Yes Rerun Controls, Acceptable? Yes Rerun patient specimens report new results No Call Manufacturer for technical assistance. Store frozen or send out all patient specimens until instrument has been repaired. No patient testing is done if controls remain outside of acceptable limits. The Laboratory Technical Supervisor will notify providers as needed. Rejection criteria for quality control 1. Two or more levels of control are outside the instruments acceptable range 2. Two levels are within 2SD, but the third level is outside 3SD *****Document all actions taken***** All quality control testing is recorded for each test. As new lot numbers of control ore reagents are introduced information will be documented. Instrument maintenance records with corrective action are also maintained." The laboratory failed to state that ALL patient test results obtained in the unacceptable test run AND since the last acceptable test run must be evaluated. 2. Review of ADVIA Centaur quality control (QC) records revealed test system adjustments performed for the following sampling of QC test events in 2022 and 2023: Liquichek Immunoassay Plus Control (put into use 11/15 /2022): Level 1 Lot #85331; expiration date: 08/31/2024 Level 2 Lot #85332; expiration date: 08/31/2024 Level 3 Lot #85333; expiration date: 08/31/2024 12/15 /2022 DHEA analyte 7:52 am QC level 1 failed 7:57 am QC level 2 failed 8:47 am QC level 1 & 2 were repeated and failed 8:47 am QC level 3 failed 9:53 am DHEA

was calibrated, and calibration passed 10:22 am QC level 1 was repeated and passed 10:24 am QC level 2 was repeated and passed 10:25 am QC level 3 was repeated and passed Review of corrective action log stated: "DHEA out all 3 levels X 2"; "Calibrate /rerun - Ok" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/14/2022): Specimen IDs: 00217041, 00223702, 00223677, 00217802, 00218885, 00223655, 00217717, 00218885, 00208303, 00221803 3/24/2023 Vitamin B12 analyte 1:00 pm QC level 1 failed 1:05 pm QC level 2 failed 1:10 pm QC level 3 failed 1:35 pm Vitamin B12 was calibrated 1:57 pm QC level 2 was repeated and failed 1:58 pm QC level 2 was repeated and failed 1:58 pm QC level 3 was repeated and failed 1:59 pm QC level 3 was repeated and failed 2:41 pm QC level 1 was repeated and failed 2:41 pm QC level 1 was repeated and passed Review of corrective action log stated: "VB12 controls out 3SD (all) Calibrate & repeat - 2/3 out still"; "No Vit B12 ran on patient samples" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (3/23/2023): Specimen IDs: 00227301, 00227280, 002214992, 00219965 3/27/2023 DHEA analyte 7:34 am QC level 2 failed 7:38 am QC level 3 failed 8:05 am QC level 1 failed 8:07 am QC level 2 was repeated and failed 9:26 am DHEA was calibrated, and calibration failed 10:23 am DHEA was calibrated, and calibration failed 10:48 am DHEA was calibrated, and calibration passed 11:17 am QC level 1 was repeated and passed 11:18 am QC level 2 was repeated and passed 11:46 am QC level 3 was repeated and passed Review of corrective action log stated: "DHEA all levels out for QC - calibrate - failed new calibrator- still out new reagent pack- cal good" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (3/24/2023): Specimen IDs: 00222031, 00223930, 00225943, 00221535, 00218433, 00224518, 00227359, 00227373, 00223658, 00226972, 00221564, 00219659, 00222001, 00221301, 00225435, 00225275, 00222914, 00227411, 00227406 3/29/2023 LH analyte 7:56 am QC level 1 failed 8:02 am QC level 2 failed 8:06 am QC level 3 failed 8:35 am QC level 1 was repeated and passed 8:36 am QC level 2 and 3 were repeated and failed 8:37 am QC level 3 was repeated and failed 9:04 am LH was calibrated, and calibration passed 10:44 am QC level 2 was repeated and failed 10:45 am QC level 3 was repeated and failed 11:12 am QC level 2 was repeated and failed 11:50 am QC level 2 was repeated and passed 11:51 am QC level 3 was repeated and passed Review of corrective action log stated: "LH/TESTOS out QC - calibrate - still out new QC material - In range ok" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (3/28/2023): Specimen IDs: 00221457, 00227445 3/29/2023 Testosterone analyte 7:55 am QC level 1 failed 8:00 am QC level 2 passed 8:05 am QC level 3 failed 8:35 am QC level 1 was repeated and failed 8:36 am QC level 3 was repeated and failed 9:05 am Testosterone was calibrated, and calibration failed 10:18 am Testosterone was calibrated, and calibration passed 10:44 am QC level 1 was repeated and failed 10:45 am QC level 3 was repeated and passed 11:11 am QC level 1 was repeated and failed 11:50 am QC level 1 was repeated and failed 12:23 pm QC level 1 was repeated and failed 1:16 pm QC level 1 was repeated and passed Review of corrective action log stated: "LH/TESTOS out QC - calibrate - still out new QC material - In range ok" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (3/28/2023): Specimen IDs: 00221457, 00220139, 00227428, 00221253, 00227460, 00225890, 0022596, 00227143, 00227423, 00221412, 00221170, 00226916, 00226617, 00224828, 00227428, 00227142, 00224995, 00221004, 00221435, 00227445, 00221411, 00220789, 00227419, 00221417, 00221386 3. During an interview on 04/30/2023 at 1:40 pm, the Technical

Consultant confirmed the above findings. Word Key: DHEA-
Dehydroepiandrosterone-Sulfate LH- luteinizing hormone Testos- testosterone Cal-
calibrate