Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1065032	02/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Fem Centre	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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS-209 form, review of College of American Pathologists (CAP) proficiency testing (PT) records from 2024, and confirmed in interview, the laboratory failed to ensure three of three consecutive hematology PT events were analyzed by personnel who routinely perform hematology testing in the laboratory. Findings include: 1. Review of the laboratory's submitted CMS-209 form determined the laboratory identified two testing persons performing hematology testing. 2. Review of CAP PT records from 2024 determined Testing Person-2 (as listed on the CMS-209 form) tested the following PT events: 2024 Hematology 1st event 2024 Hematology 2nd event 2024 Hematology 3rd event 3. Testing-person 1 (as listed on the CMS-209 form) confirmed the findings during an interview on 02/20/2025 at 1205 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, review of the manufacturer's package insert, review of quality control (QC) records from December 2024 (random review), review of patient final reports, and staff interview, the laboratory failed to have a mechanism in place to monitor QC for immediate error for one of one BioRad Liquichek Immunoassay Plus Control lots for the analyte estradiol reviewed in December 2024 (random review) to ensure accurate and reliable test results. Findings include: 1. Review of the laboratory's policy titled "Quality Control", approved by the laboratory director on 03/24/2009 stated: "Definitions: Acceptable Range: ...defined by the laboratory through repetitive testing and calculated Standard Deviations." 2. Review of the manufacturer's package insert "BioRad Liquichek Immunoassay Plus Control Levels 1, 2, and 3" stated: "ASSIGNMENT OF VALUES The mean values and corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product." Further review of the manufacturer's package insert determined QC values were established by the manufacturer at +/- 3SD ranges for the Siemens Advia Centaur Systems for the analyte estradiol: a) Lot 85380 - Expires: 11/30/2025 Level 1: Mean: 64.3 pg/mL 3SD range: 43.5 - 85.1 pg/mL Level 2: Mean: 457 pg/mL 3SD range: 387 - 527 pg/mL Level 3: Mean: 1333 pg/mL 3SD range: 1152 - 1514 pg/mL 3. Review of the laboratory's QC records from December 2024 (random review) determined the ranges used by the laboratory for the analyte estradiol were too wide to detect immediate error: a) Lot: 83580 - Expires 11/30/2025 Level 1: mean: 64.3 pg/mL 2SD: 20.8 pg /mL Laboratory's 2SD range: 43.5 - 85.1 pg/mL Level 2: mean: 457.0 pg/mL 2SD: 70.0 pg/mL 2SD range: 387 - 527 pg/mL Level 3: mean: 1333.0 pg/mL 2SD: 181.0 pg /mL 2SD range: 1152 - 1514 pg/mL 4. Review of patient final reports from December 2024 (random review) determined Estradiol testing was performed on the following patients: a) Accession #: 245920 Collection: 12/02/2024 08:12 AM Performed: 12/02 /2027 12:41 PM Result: 20.2 pg/mL b) Accession #: 247876 Collection: 12/02/2024 09:10 AM Performed: 12/02/2027 12:44 PM Result: 168.7 pg/mL c) Accession #: Collection: 12/02/2024 11:50 AM Performed: 12/02/2027 01:17 PM Result: 59.3 pg /mL d) Accession #: 248066 Collection: 12/04/2024 12:36 PM Performed: 12/04/2024 01:42 PM Result: 105.2 pg/mL e) Accession #: 248078 Collection: 12/05/2024 09:33 AM Performed: 12/06/ 01:36 PM Result: 77.7 pg/mL f) Accession #: 243775 Collection: 12/05/2024 10:09 AM Performed: 12/05/2024 11:21 AM Result: 103.2 pg /mL g) Accession #: 241833 Collection: 12/05/2024 10:40 AM Performed: 12/05 /2024 11:02 AM Result: 73.5 pg/mL h) Accession #: 248021 Collection: 12/05/2024 01:51 PM Performed: 12/05/2024 03:10 PM Result: 22.9 pg/mL i) Accession #: 242019 Collection: 12/17/2024 02:01 PM Performed: 12/17/2024 02:18 PM Result: 46.2 pg/mL j) Accession #: 243328 Collection: 12/20/2024 09:52 AM Performed: 12 /20/2024 01:53 PM Result: 34.7 pg/mL k) Accession #: 243467 Collection: 12/23 /2024 08:07 AM Performed: 12/23/2024 10:14 AM Result: 39.9 pg/mL 5. Testing-person 1 (as listed on the CMS-209 form) confirmed the findings during an interview on 02/20/2024 at 1430 hours in the office. Key: SD - standard deviations pg/mL - picograms per milliliter CMS - Centers for Medicare and Medicaid Services

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS-209 form, review of laboratory personnel records, and confirmed in interview, the technical consultant failed to evaluate the annual competency of one of two testing persons in 2023 and 2024. Findings include: 1. Review of the laboratory's submitted CMS-209 form identified two testing persons performing non-waived testing. 2. Review of the laboratory's personnel records determined the laboratory failed to ensure the six required elements of competency for non-waived testing for Testing Person-2 (as listed on the CMS-209 form) were documented for one of one event in 2023 and one of one event in 2024. The laboratory was asked to provide documentation of assessing the six required elements of competency for non-waived testing for Testing Person-2 in 2023 and 2024. No documentation was provided. 3. Testing Person-1 (as listed on the CMS-209 form) confirmed the findings during an interview on 02/20/2025 at 1204 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services