Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1065032	08/19/2021
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	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 493.1403 Laboratory Director, (moderate complexity). Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of manufacturer's instructions, laboratory's stability studies, corrective action logs, patient final reports, and confirmed in staff interview, the laboratory failed to meet the requirements of the preanalytical phase of testing as

	evidenced by: 1. The laboratory failed to have documentation of performing stability studies to support its policy of freezing (-10 C to -25 C) patient glucose specimens overnight for next day analysis. Refer to D5311.
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 review of manufacturer's instructions, laboratory's stability studies for Horiba ABX Pentra 400 chemistry analyzer, Horiba ABX Pentra 400 corrective action log (04/01/2021-08/16/2021), laboratory's patient final reports (7/2/2021), and staff interview, it was revealed the laboratory failed to have documentation of performing stability studies to support its policy of freezing glucose specimens (-10 C to -25 C) overnight for next day analysis. Findings Included: 1. Review of manufacturer's instructions for the Horiba ABX Pentra 400 Glucose reagent (Form 0846 Revision 2) revealed the following: "The stability of glucose in specimens depends on the storage temperature, bacterial contamination and glycolyse. Stability: Serum/Plasma: The plasma or serum specimen without preservative should be separated from the cells or blood clot in the half hour following the taking. In the uncentrifuged blood, at room temperature, the average decrease of glucose in serum is about 7% per hour. This decrease results from glycolyse." 2. Review of laboratory stability studies for the Horiba ABX Pentra 400 chemistry analyzer revealed the following acceptable stability for glucose specimens: "GLU(Glucose) Stability: 8 hours RT (Room Temperature); 2 days Ref (Refrigerated)" The laboratory failed to provide documentation of stability studies performed on glucose specimens frozen at -10 C to -25 C prior to analysis. 3. Random review of Horiba ABX Pentra 400 corrective action log (04/01/2021-08/16/2021) revealed the following: "07/02/2021- Reagent Cassette Issues; Froze all samples (-10 C to -25 C) for Chemistry-Ok on Tuesday" 4. A sampling of final patient reports revealed the following glucose specimens were processed on 7/03/2021 after being frozen at -10 C to -25 C overnight (07/02/2021): a. Patient ID: 06-9382 b. Patient ID: 120982 c. Patient ID: 61098 d. Patient ID: 115517 e. Patient ID: 140216 f. Patient ID: 130239 g. Patient ID: 67898 h. Patient ID: 68187 i. Patient ID: 67643 5. In an interview with the laboratory manager on 8/18/21 at 01: 15 PM in the facility office, the laboratory manager stated if there were issues with the Horiba ABX Pentra analyzer or if specimens arrived after 4:00 PM, the specimens were frozen at -10 C to -25 C for next day analysis. The laboratory manager was asked to provide documentation to support the laboratory's policy of freezing (-10 C to -25 C) glucose specimens overnight for next day analysis. No documentation was provided. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the operator's manual for the Advia Centaur Immunoassay analyzer, random review of laboratory environmental records (5/2020, 9/2020, 7/2021 and 8/2021) and confirmed in staff interview, the laboratory failed to ensure the room temperature range was within manufacturer's specifications for operating conditions for 4 of 4 months. Findings Included: 1. The operator's manual for the Advia Centaur Immunoassay analyzer (Revised 11-2008) stated the following operating temperature range: "Appendix E: Specifications Environmental Specifications: Temperature- 18 to 30 C" 2. A random review of the laboratory's environmental records (5/2020, 9/2020, 7/2021 and 8/2021) revealed the laboratory defined their acceptable temperature range as 16-32 C. The laboratory failed to ensure their room temperature range was within manufacturer's specifications. 3. In an interview with the laboratory manager on 8/18/21 at 03:10 PM in the laboratory, after presentation of findings, the laboratory manager confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the submitted Centers for Medicare and Medicaid (CMS) 116 Application, random review of final patient reports and interview with staff, it was revealed that the laboratory failed to ensure the correct laboratory address for all tests performed was documented on the final patient reports for 4 of 4 patients. Findings Included: 1. Review of the Centers for Medicare and Medicaid (CMS) 116 Application (Submitted at time of survey on 08/18/2021) revealed the following correct physical address for the performing laboratory: "6221 Colleyville Blvd., Suite 150 Colleyville, TX 76034" 2. Random review of final patient reports revealed the following listed address for the performing laboratory: "6225 Colleyville Blvd., Suite 100 Colleyville, TX 76034" The performing laboratory failed to provide the correct physical address of the laboratory on the final patient report. Further review of final patient reports revealed the following 4 of 4 patient reports with the incorrect physical address listed: a. Patient ID: 136115 b. Patient ID: 06-0536 c. Patient ID: 68187 d. Patient ID: 67643 3. In an interview with the laboratory manager on 8/18/21 at 03:10 PM, in the laboratory, after presentation of findings, the laboratory manager confirmed the above findings.

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 review of laboratory's policy, manufacturer's instructions, patient test records, and quality control records, the laboratory director failed provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure quality laboratory services for moderate complexity preanalytic systems. Refer to D6007.
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 review of the manufacturer's instructions, laboratory's stability studies, corrective action logs, patient final reports the laboratory director failed to ensure quality laboratory services for moderate complexity preanalytic systems, as evidenced by: 1. The laboratory failed to have documentation of performing stability studies to support its policy of freezing (-10 C to -25 C) patient glucose specimens overnight for next day analysis. Refer to D5311
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the submitted Centers for Medicare and Medicaid (CMS) 116 Application, random review of final patient reports and interview with staff, it was revealed that the laboratory failed to ensure the correct laboratory address for all tests performed was documented on the final patient reports for 4 of 4 patients. Refer to D5805.