Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1065032	09/06/2019
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	Entrance and exit conferences were held with the laboratory technical consultant. 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 representative at the entrance and exit conferences. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
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 Medonic M Series hematology analyzer manufacturer's instructions, and random review of patient records from 07/2019, 09/03/2019 through 09/05/2019, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for specimen stability for 37 of 81 patients tested for

Complete Blood Count (CBC) testing. Findings included: 1. The manufacturer's instructions for the Medonic M Series (PN203129A R12.13.10) hematology analyzer stated the following in the section titled "Specimen Requirements/Patient Preparation": "For optimum results, the sample should be gently mixed for 10-15 minutes on a mixer and should be analyzed between 15 minutes and 6 hours stored at room temperature. Failure to mix properly or count in the required time limit may produce erroneous results." 3. Random review of patient records from 07/2019, 09/03 /2019 through 09/05/2019, revealed the laboratory failed to ensure that the following 37 of 81 patients were tested for CBC within 6 hours: Patient 172569; CBC specimen collected 07/02/2019 0922 hours; CBC performed 07/02/2019 1618 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 176300; CBC specimen collected 07/02/2019 0955 hours; CBC performed 07/02/2019 1618 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 177955; CBC specimen collected 07/02/2019 1005 hours; CBC performed 07/02/2019 1623 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178216; CBC specimen collected 07/02 /2019 0850 hours; CBC performed 07/02/2019 1640 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178425; CBC specimen collected 07/02/2019 1020 hours; CBC performed 07/02/2019 1622 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 176113; CBC specimen collected 07/03/2019 0906 hours; CBC performed 07 /03/2019 1606 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178473; CBC specimen collected 07/03/2019 0949hours; CBC performed 07/03/2019 1606 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 175348; CBC specimen collected 07/08 /2019 0842 hours; CBC performed 07/08/2019 1547 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 172520; CBC specimen collected 07/09/2019 0848 hours; CBC performed 07/09/2019 1540 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 175329; CBC specimen collected 07/09/2019 0937 hours; CBC performed 07 /09/2019 1547 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178233; CBC specimen collected 07/09/2019 0822 hours; CBC performed 07/09/2019 1542 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 167505; CBC specimen collected 07/10 /2019 0816 hours; CBC performed 07/19/2019 1546 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 177148; CBC specimen collected 07/10/2019 0846 hours; CBC performed 07/10/2019 1541 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178448; CBC specimen collected 07/10/2019 1030 hours; CBC performed 07 /10/2019 1659 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 170710; CBC specimen collected 07/11/2019 0854 hours; CBC performed 07/11/2019 1602 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 171762; CBC specimen collected 07/11 /2019 0842 hours; CBC performed 07/11/2019 1557 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 177554; CBC specimen collected 07/11/2019 0903 hours; CBC performed 07/11/2019 1601 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178527; CBC specimen collected 07/12/2019 0830 hours; CBC performed 07 /12/2019 1546 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 177640; CBC specimen collected 07/16/2019 0851 hours; CBC performed 07/16/2019 1545 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 177640; CBC specimen collected 07/16 /2019 0950 hours; CBC performed 07/16/2019 1547 hours The patient specimen was

	tested at the facility more than 6 hours after collection. Patient 177924; CBC specimen collected 07/17/2019 0946 hours; CBC performed 07/17/2019 1548 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178892; CBC specimen collected 07/17/2019 0936 hours; CBC performed 07 /17/2019 1550 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178725; CBC specimen collected 07/18/2019 0807 hours; CBC performed 07/18/2019 1622 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 178994; CBC specimen collected 07/19 /2019 0930 hours; CBC performed 07/19/2019 1547 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 179042; CBC specimen collected 07/22/2019 0928 hours; CBC performed 07/22/2019 1555 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 179127; CBC specimen collected 07/24/2019 0933 hours; CBC performed 07 /24/2019 1542 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 172463; CBC specimen collected 07/25/2019 0849 hours; CBC performed 07/25/2019 1555 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 172463; CBC specimen collected 07/25 /2019 0926 hours; CBC performed 07/25/2019 1548 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 179189; CBC specimen collected 07/26/2019 0831 hours; CBC performed 07/26/2019 1549 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 172481; CBC specimen collected 09/03/2019 0905 hours; CBC performed 09 /03/2019 1609 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 174315; CBC specimen collected 09/03/2019 0837 hours; CBC performed 09/03/2019 1644 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 179443; CBC specimen collected 09/03 /2019 0827 hours; CBC performed 09/03/2019 1643 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 180519; CBC specimen collected 09/03/2019 1006 hours; CBC performed 09/03/2019 1643 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 180520; CBC specimen collected 09/03/2019 1025 hours; CBC performed 09 /03/2019 1702 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 174508; CBC specimen collected 09/04/2019 0934 hours; CBC performed 09/04/2019 1546 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 171092; CBC specimen collected 09/05 /2019 0808 hours; CBC performed 09/05/2019 1537 hours The patient specimen was tested at the facility more than 6 hours after collection. Patient 179473; CBC specimen collected 09/05/2019 0917 hours; CBC performed 09/05/2019 1552 hours The patient specimen was tested at the facility more than 6 hours after collection 4. The findings were confirmed by the Technical Consultant in an interview on 09/06 /2019 at 1330 hours.
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 direct observation, review of laboratory policy, manufacturer's instructions for the Bio-Rad Liquidchek Immunoassay Plus Quality Control (QC) material, a random review of laboratory environmental records (07/2019-08/2019) and confirmed in interview, the laboratory failed to ensure freezer ranges were within specification requirements for the Bio-Rad Liquidchek Immunoassay Plus QC material for 23 of 42 days. Finding included: 1. Observed during a tour of the laboratory on 09/06/2019 at 0920 hours was a Frigidaire Frost Free refrigerator/freezer. The following Liquidchek Immunoassay Plus QC material was stored in the frost-free freezer: 18 Unopened vials Lot number 40971; Expiration date 2020-06-30 20 Unopened vials Lot number 40972; Expiration date 2020-06-30 20 Unopened vials Lot number 40971; Expiration date 2020-06-30 2. The laboratory policy titled "Manufacturer's Guidelines" (Signed by the laboratory director 03/24/2019) stated, "FEM laboratory will follow all manufacturer's guidelines pertaining to the Pre-analytical, Analytical, Post-analytical stages of specimen collections. All manufacturers' guidelines will also be followed concerning reagents, quality control material and calibration material to ensure precise and accurate results." 3. Review of the manufacturer's instructions (2018-04) for Liquidchek Immunoassay Plus QC material stated, "Storage and Stability: This product will be stable until the expiration date when stored unopened at -20 to -70 C." 4. Review of laboratory environmental records from 07/2019 through 08/2019 revealed the following 23 of 42 days when the freezer temperature was NOT within the -20 to -70 C specification requirements for the Bio-Rad Liquidchek Immunoassay Plus QC material: 07/02/2019; -19.0C 07/09/2019; -18.0C 07/10/2019; -18.8C 07/11 /2019; -18.3C 07/17/2019; -15.3C 07/19/2019; -16.7C 07/22/2019; -19.0C 07/24 /2019; -17.2C 07/25/2019; -17.6C 07/31/2019; -19.3C 08/02/2019; -18.4C 08/05 /2019; -19.0C 08/06/2019; -17.8C 08/08/2019; -18.6C 08/09/2019; -18.6C 08/12 /2019; -19.6C 08/13/2019; -18.2C 08/14/2019; -18.4C 08/16/2019; -18.0C 08/20 /2019; -14.9C 08/21/2019; -16.6C 08/23/2019; -16.0C 08/30/2019; -19.0C 4. The findings were confirmed by the Technical Consultant on 09/06/2019 at 0930 hours during a tour of the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory policy, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that 3 of 3 vials of Bio-Rad Liquidchek Immunoassay Plus Quality Control (QC) material were labeled with new expiration dates according to the manufacturer. Findings included: 1. Observed in the laboratory refrigerator on 09/06/2019 at 1300 hours were the following 3 vials of reconstituted Liquidchek Immunoassay Plus QC material: Lot number 40971; Expiration date 2020-06-30; Opened 09/02/2019 Lot number 40972; Expiration date 2020-06-30; Opened 08/30/2019 Lot number 40971; Expiration date 2020-06-30; Opened 08/30/2019 The vials were NOT labeled with the new expiration date. 2. Review of the following laboratory policies revealed: a. Laboratory policy

titled "Opening of Reagents" (Signed by the laboratory director 03/24/2019) stated, "It is the policy of the FEM laboratory to document the dates on all reagents, kit tests, or any other materials used in patient testing with the received, opened, and expiration dates. This policy will be followed to ensure optimal patient testing." b. Laboratory policy titled "Manufacturer's Guidelines" (Signed by the laboratory director 03/24 /2019) stated, "FEM laboratory will follow all manufacturer's guidelines pertaining to the Pre-analytical, Analytical, Post-analytical stages of specimen collections. All manufacturers' guidelines will also be followed concerning reagents, quality control material and calibration material to ensure precise and accurate results." c. Laboratory policy titled "General Laboratory Polices" (Signed by the laboratory director 03/24 /2019) stated, "7. All reagents, test kits, calibration material, control material, supplies, ect, are to be marked with date received and date opened. All expiration dates will be observed. All reagents, test kits, calibration material, control material, supplies, ect, will be discarded when expired." 3. Review of the manufacturer's instructions (2018-04) for Liquidchek Immunoassay Plus QC material stated, "Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 C, this product will be stable as follows: All analytes 14 days. Except: Estradiol: 5days, Folate: 4 days. Date of thaw should be noted." 4. The findings were confirmed by the Technical Consultant on 09/06/2019 at 1310 hours during a tour of the laboratory. II. Based on direct observation, review of laboratory policy, and staff interview, it was revealed the laboratory failed to ensure that 3 of 3 vials of ABX Pentra Quality Control (QC) and Calibration material were labeled with new or correct expiration dates according to the manufacturer. Findings included: 1. Observed in the laboratory refrigerator on 09/06/2019 at 1300 hours were the following 3 vials of reconstituted ABX Pentra QC and calibration material: a. QC material: Lot number 1802701; Expiration date 2019-09-17; Opened 09/06/2019; Expiration 09/20/2019 QC material labeled with an INCORRECT expiration date. b. QC material: Lot number 1800201; Expiration date 2019-09-17; No opened or new expiration date c. Calibration material: Lot number 180690; Expiration date 2020-09-17; Opened 09/03/2019 The vials were NOT labeled with the new or correct expiration date. 2. Review of the following laboratory policies revealed: a. Laboratory policy titled "Opening of Reagents" (Signed by the laboratory director 03/24/2019) stated, "It is the policy of the FEM laboratory to document the dates on all reagents, kit tests, or any other materials used in patient testing with the received, opened, and expiration dates. This policy will be followed to ensure optimal patient testing." b. Laboratory policy titled "Manufacturer's Guidelines" (Signed by the laboratory director 03/24/2019) stated, "FEM laboratory will follow all manufacturer's guidelines pertaining to the Pre-analytical, Analytical, Post-analytical stages of specimen collections. All manufacturers' guidelines will also be followed concerning reagents, quality control material and calibration material to ensure precise and accurate results." c. Laboratory policy titled "General Laboratory Polices" (Signed by the laboratory director 03/24 /2019) stated, "7. All reagents, test kits, calibration material, control material, supplies, ect, are to be marked with date received and date opened. All expiration dates will be observed. All reagents, test kits, calibration material, control material, supplies, ect, will be discarded when expired." 3. Review of the manufacturer's instructions for ABX Pentra QC (2018/10/05) material stated the following: "Stability parameters after reconstitution of ABX Pentra Control: 5 days at 2-8 C; Stability of total bilirubin following reconstitution: 24 hours at 2-8 C; Stability of direct bilirubin following reconstitution: 8 hours at 2-8C." 4. Review of the manufacturer's instructions for ABX Pentra MultiCal Calibration (2015/04/20) material stated the following: "Stability of components after reconstitution of ABX Pentra MultiCal: 2 days at 2-8 C; Stability of direct bilirubin following reconstitution: 8 hours at 2-8 C; Stability of total bilirubin following reconstitution: 1 day at 2-8C." 5. The findings

	were confirmed by the Technical Consultant on 09/06/2019 at 1310 hours during a tour of the laboratory. III. Based on direct observation, review of laboratory policy, and staff interview, it was revealed the laboratory failed to ensure that 1 of 1 box of Siemens DCA Hemoglobin A1C reagent cartridges were labeled with new expiration dates according to the manufacturer. Findings included: 1. Observed on 09/06/2019 at 1300 hours on the laboratory counter at room temperature was 1 opened box of Siemens DCA Hemoglobin A1C reagent cartridges (Lot number 0238; Expiration date 07/2021). The box was NOT labeled with the open date or new expiration date. 2. Review of the following laboratory policies revealed: a. Laboratory policy titled "Opening of Reagents" (Signed by the laboratory director 03/24/2019) stated, "It is the policy of the FEM laboratory to document the dates on all reagents, kit tests, or any other materials used in patient testing with the received, opened, and expiration dates. This policy will be followed to ensure optimal patient testing." b. Laboratory policy titled "Manufacturer's Guidelines" (Signed by the laboratory director 03/24 /2019) stated, "FEM laboratory will follow all manufacturer's guidelines pertaining to the Pre-analytical, Analytical, Post-analytical stages of specimen collections. All manufacturers' guidelines will also be followed concerning reagents, quality control material and calibration material to ensure precise and accurate results." c. Laboratory policy titled "General Laboratory Polices" (Signed by the laboratory director 03/24 /2019) stated, "7. All reagents, test kits, calibration material, control material, supplies, ect, are to be marked with date received and date opened. All expiration dates will be observed. All reagents, test kits, calibration material, control material, supplies, ect, will be discarded when expired." 3. Review of the manufacturer's instructions for Siemans DCA Hemoglobin A1C stated, "Storage: Store reagent cartridges at 2-8 C; Reagent cartridges can be kept for up to three months at room temperature any time before the expiration date. Record on the carton, the date the carton was placed at room temperature." 4. The findings were confirmed by the Technical Consultant on 09/06/2019 at 1310 hours during a tour of the laboratory.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review Centers for Medicare and Medicaid (CMS)-209 form, testing personnel records and staff interview, the laboratory director failed to ensure 1 of 4 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 1 of 4 testing persons met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #4 listed to perform moderate complexity testing. 2. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: a. Testing person #3; No education documents provided 3. The above findings were confirmed by the Technical Consultant in an interview on 09/06/2019 at 1300 hours in the facility office.