Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464567	06/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Woman's Clinic, The	711 St John Street, Monroe, LA	

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	A Certification Survey was performed on June 11, 2019 at The Women's Clinic, CLIA ID # 19D0464567. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on June 11, 2019 revealed the following expired items located on a phlebotomy tray: a) BD Vacutainer SST 3.5 mL blood collection tubes, Lot # 8003589, Expiration date 12/31/18, Quantity: six (6) tubes 2. In interview on June 11, 2019 at 10:35am, Personnel 5 stated the blood collection tubes are used to draw patients during clinic hours. Personnel 5 confirmed the identified items were expired and in place for patient testing.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform corrective actions when the cuvette temperature failed to be within acceptable range as required by the manufacturer for the Siemens Dimension Xpand Plus Chemistry analyzer. Findings: 1. Observation by surveyor during laboratory tour on June 11, 2019 revealed the laboratory utilized the Siemens Dimension Xpand Plus analyzer for chemisty testing. 2. Review of the Siemens Dimension Xpand Plus analyzer maintenance logs revealed the acceptable cuvette temperature range as 36.8 to 37.2 degrees Celsius. 3. Further review of the maintenance logs revealed the laboratory did not take corrective action when the cuvette temperature was out of range for the following one (1) of twenty four (24) days reviewed: a) November 7, 2018 -- temperature recorded as 36.7 degrees celsius 4. In interview on June 11, 2019 at 3:00 pm, Personnel 3 confirmed the laboratory did not have documentation of corrective action for unacceptable cuvette temperature.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5417.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.

D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Technical Consultant failed to provide technical and scientific oversight of the laboratory. Findings: 1. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417. 2. The laboratory failed to perform corrective actions when the cuvette temperature failed to be within acceptable range as required by the manufacturer for the Siemens Dimension EXL with LM Chemistry analyzer. Refer to D5781.